UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

QINGPING ZHU, Derivatively on Behalf of SAGE THERAPEUTICS, INC.,

Plaintiff,

v.

BARRY E. GREENE, KIMI IGUCHI, AL ROBICHAUD, JIM DOHERTY, STEPHEN J. KANES, LAURA GAULT, ELIZABETH BARRETT, MICHAEL F. COLA, JESSICA FEDERER, JAMES M. FRATES, GENO GERMANO, GEORGE GOLUMBESKI, JEFFREY M. JONAS, STEVEN PAUL, and KEVIN P. STARR,

Defendants,

and

SAGE THERAPEUTICS, INC.,

Nominal Defendant.

Case No. 1:25-cv-02498

DEMAND FOR JURY TRIAL

VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

Plaintiff Qingping Zhu ("Plaintiff"), by and through his undersigned attorneys, brings this verified stockholder derivative action on behalf of nominal defendant Sage Therapeutics, Inc. ("Sage" or the "Company"), against certain of the Company's executive officers and its Board of Directors (the "Board") for breaches of fiduciary duties and violations of federal law by the Individual Defendants (defined below). Plaintiff's allegations are based on personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, based on, *inter alia*, the investigation conducted by his counsel, including review of publicly available information regarding the Company; the allegations of a class action complaint filed in the securities class action captioned *In re Sage Therapeutics, Inc. Securities Litigation, et al.*, Case No. 1:24-cv-

06511-JAV (S.D.N.Y. Aug. 28, 2024) (the "Securities Class Action"); conference call transcripts and announcements; filings with the United States Securities and Exchange Commission (the "SEC"); press releases disseminated by Sage; legal filings; news reports; and securities analysts' reports about the Company.

NATURE OF THE ACTION

1. This is a shareholder derivative action brought in the right, and for the benefit, of Sage against the Individual Defendants, certain of Sage's officers and directors, seeking to remedy their violations of federal law and breaches of fiduciary duty that have occurred from at least April 12, 2021 to July 23, 2024 (the "Relevant Period"), and have caused, and continue to cause, substantial harm to Sage and its shareholders.

2. Sage is a biopharmaceutical company that develops therapies to treat neurological and psychiatric conditions, including major depressive disorder ("MDD"), postpartum depression ("PPD"), and other mood disorders.

3. Throughout the Relevant Period, Company management issued materially false and misleading statements regarding Sage's three primary drug candidates: zuranolone, SAGE-718, and SAGE-324. Zuranolone was the Company's flagship drug, designed for the treatment of MDD and PPD. SAGE-718 was designed for the treatment of various cognitive disorders, including Parkinson's Disease and Alzheimer's Disease. SAGE-324 was designed for the treatment of essential tremor.

4. Sage's senior leadership repeatedly overstated the efficacy, safety, durability, and commercial prospects of its three primary drug candidates. Further, the Company's officers and directors concealed issues with the methodology employed in Sage's clinical trials and overstated the likelihood that the Company would secure United States Food and Drug Administration

("FDA") approval for its drug candidates.

5. At the end of the Relevant Period, the public would learn that the FDA had denied approval of zuranolone for use in the treatment of MDD because it lacked long-term efficacy and had significant safety concerns. While the FDA did approve zuranolone for use in the treatment of PPD, the Company had consistently represented throughout the Relevant Period that MDD constituted the largest market and the most lucrative opportunity for zuranolone. Accordingly, the market reacted negatively to the FDA denial.

6. Investors and the market were also shocked to learn at the end of the Relevant Period that the Company would be abandoning the development of SAGE-718 and SAGE-324 due to poor performance of the drugs in clinical trials.

7. As a direct and proximate result of the misconduct detailed herein, the Company has incurred significant financial losses, including the cost of defending itself and, potentially, incurring class-wide damages in the Securities Class Action, as well as additional losses in market capitalization, reputational harm and the loss of goodwill.

8. Moreover, in light of the breaches of fiduciary duty by the Individual Defendants, most of whom are the Company's current directors, their collective engagement in fraud, the substantial likelihood of the directors' liability in this derivative action and the Securities Class Action, and that the Individual Defendants are beholden to each other based on their longstanding business and personal relationships, the Individual Defendants do not possess the requisite level of disinterestedness and independence to consider a demand to commence litigation against themselves and the other Individual Defendants on behalf of the Company. Accordingly, Plaintiff did not make a demand on the Board because, as further detailed herein, demand would be a futile and useless act.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and Section 27 of the Securities Exchange Act of 1934 (the "Exchange Act") over the claims asserted herein for violations of Section 14(a) of the Exchange Act (15 U.S.C. §§ 78n(a)) and Rule 14a-9 (17 C.F.R.§240.14a-9).

10. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. §1367(a).

11. In connection with the acts, conduct and other wrongs complained of herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, the United States mail, and the facilities of a national securities market.

12. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

13. This Court has personal jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in this District or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the courts of this District permissible under traditional notions of fair play and substantial justice.

14. Venue is proper in this district pursuant to Section 27(a) of the Exchange Act and 28 U.S.C. §1391 because Defendants have conducted business in this District and a substantial portion of the transaction and wrongs complained of herein occurred in this District.

PARTIES

Plaintiff

15. Plaintiff is, and has been at all relevant times, a shareholder of Sage.

Nominal Defendant

16. Nominal Defendant Sage is incorporated under the laws of Delaware, with its principal executive offices located at 55 Cambridge Parkway, Cambridge, Massachusetts. Sage common stock trades on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "SAGE."

Individual Defendants

17. Defendant Barry E. Greene ("Greene") has served as the Company's Chief Executive Officer ("CEO") since December 2020 and as a member of the Board since October 2020. Defendant Greene is named as a defendant in the Securities Class Action. According to the Company's public filings, Defendant Greene received $58,864,150 in 2021, $5,705,164 in 2022, and $6,237,491 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Greene beneficially owned 655,176 shares of Sage common stock, worth roughly $11.7 million[1] and constituting 1.1% of the Company's total outstanding shares.

18. Defendant Elizabeth Barrett ("Barrett") has served as a member of the Board since January 2019 and serves as a member of the Audit Committee. According to the Company's public filings, Defendant Barrett received $540,860 in 2021, $267,376 in 2022, and $425,050 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Barrett beneficially owned 65,910 shares of Sage common stock, worth roughly $1.2 million.

19. Defendant Michael F. Cola ("Cola") has served as a member of the Board since September 2014 and served as a member of the Audit Committee during the Relevant Period. According to the Company's public filings, Defendant Cola received $552,527 in 2021, $274,857

[1] Valuations of the Individual Defendants' personal holdings of Company stock are based on the $17.90 per share closing price of Sage stock on April 1, 2024, the following trading day after March 31, 2024.

in 2022, and $440,050 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Cola beneficially owned 112,624 shares of Sage common stock, worth roughly $2 million.

20. Defendant Jessica Federer ("Federer") has served as a member of the Board since March 2023 and serves as a member of the Audit Committee. According to the Company's public filings, Defendant Federer received $962,227 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Federer beneficially owned 7,737 shares of Sage common stock, worth $138,492.

21. Defendant James M. Frates ("Frates") has served as a member of the Board since May 2014 and serves as Chairperson of the Audit Committee. According to the Company's public filings, Defendant Frates received $553,360 in 2021, $277,357 in 2022, and $435,050 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Frates beneficially owned 87,945 shares of Sage common stock, worth roughly $1.6 million.

22. Defendant Geno Germano ("Germano") has served as Chair of the Board since January 2024 and as a member of the Board since July 2016. According to the Company's public filings, Defendant Germano received $532,527 in 2021, $259,857 in 2022, and $417,550 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Germano beneficially owned 85,708 shares of Sage common stock, worth roughly $1.5 million.

23. Defendant George Golumbeski ("Golumbeski") has served as a member of the Board since January 2019. According to the Company's public filings, Defendant Golumbeski received $530,860 in 2021, $254,876 in 2022, and $412,550 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Golumbeski beneficially owned 73,501 shares of Sage common stock, worth roughly $1.3 million.

Former Director Defendants

24. Defendant Jeffrey Jonas ("Jonas") served as a member of the Board from August 2013 until December 2024. According to the Company's public filings, Defendant Jonas received $1,849,361 in 2022 and $496,542 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Jonas beneficially owned 771,901 shares of Sage common stock, worth roughly $13.8 million and constituting 1.3% of the Company's total outstanding shares.

25. Defendant Steven Paul ("Paul") served as a member of the Board from September 2011 until June 2024. According to the Company's public filings, Defendant Paul received $531,693 in 2021, $254,876 in 2022, and $420,050 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Paul beneficially owned 610,396 shares of Sage common stock, worth roughly $10.9 million and constituting 1% of the Company's total outstanding shares.

26. Defendant Kevin P. Starr ("Starr") served as a member of the Board from September 2011 until January 2024. According to the Company's public filings, Defendant Starr received $565,860 in 2021, $289,857 in 2022, and $420,050 in 2023 in compensation from the Company.

Officer Defendants

27. Defendant Kimi Iguchi ("Iguchi") served as the Company's Chief Financial Officer ("CFO") from March 2013 until October 2024. Defendant Iguchi is named as a defendant in the Securities Class Action. According to the Company's public filings, Defendant Iguchi received $2,423,918 in 2021, $1,624,967 in 2022, and $1,984,101 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Iguchi beneficially owned 264,892 shares of Sage common stock, worth roughly $4.7 million.

28. Defendant Al Robichaud ("Robichaud") served as the Company's Chief Scientific Officer from November 2011 until August 2023. After serving in that role, Defendant Robichaud remained a scientific consultant and a member of Sage's Medical Chemistry and Clinical Scientific Advisory Boards. Defendant Robichaud is named as a defendant in the Securities Class Action. According to the Company's public filings, Defendant Robichaud received $2,796,162 in 2021, $1,588,053 in 2022, and $3,913,495 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Robichaud beneficially owned 331,853 shares of Sage common stock, worth roughly $5.9 million.

29. Defendant Christopher Benecchi ("Benecchi") served as the Company's Chief Commercial Officer from September 2021 until October 2024. Defendant Benecchi is named as a defendant in the Securities Class Action. According to the Company's public filings, Defendant Benecchi received $2,732,430 in 2021, $1,865,704 in 2022, and $2,280,917 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Benecchi beneficially owned 53,425 shares of Sage common stock, worth $956,308.

30. Defendant Jim Doherty ("Doherty") is a founding member of Sage and has served in various roles during his tenure with the Company, including Senior Vice President of Research until 2017, Chief Research Officer until 2021, and Chief Development Officer until his departure in August 2023. Defendant Doherty is named as a defendant in the Securities Class Action.

31. Defendant Stephen J. Kanes ("Kanes") served as the Company's Chief Medical Officer from July 2013 until November 2021. Defendant Kanes is named as a defendant in the Securities Class Action.

32. Defendant Laura Gault ("Gault") has served as the Company's Chief Medical Officer since November 2022. Defendant Gault is named as a defendant in the Securities Class

Action. According to the Company's public filings, Defendant Gault received $3,967,795 in 2022 and $1,274,325 in 2023 in compensation from the Company. As of March 31, 2024, Defendant Gault beneficially owned 25,212 shares of Sage common stock, worth $451,295.

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

33. Because of their positions as officers and/or directors of Sage, and their ability to control the business and corporate affairs of the Company, the Individual Defendants owed Sage and its shareholders fiduciary obligations of good faith, loyalty, trust, and candor and were required to use their utmost ability to control and manage the Company in a fair, just, honest, and equitable manner at all relevant times.

34. Therefore, the Individual Defendants were required to act in furtherance of the best interests of Sage and its shareholders.

35. Each director and officer of the Company owes to Sage and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligation of fair dealing.

36. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Sage, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

37. Each Individual Defendant, by virtue of his or her position as a director and/or officer owed to the Company and to its shareholders the highest fiduciary duties of trust, loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and/or officers of Sage, the absence of good faith on their

part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

38. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, financial statements, earnings, internal controls, and present and future business prospects, including the dissemination of false and/or materially misleading information regarding the efficacy, safety, durability, and commercial prospects of Sage's three primary drug candidates, and the Individual Defendants had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful, accurate, and fairly presented information.

39. To discharge their duties, the officers and directors of Sage were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Sage were required to, among other things:

(a) Ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Delaware and the United States, and pursuant to Sage's own Code of Ethic and Business Conduct (the "Code of Conduct");

(b) Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;

(c) Exercise good faith to ensure that the Company's communications with the public and with shareholders are made with due candor in a timely and complete fashion;

(d) Remain informed as to how Sage conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(e) Establish and maintain systematic and accurate records and reports of the business and internal affairs of Sage and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(f) Maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Sage's operations would comply with all applicable laws and Sage's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;

(g) Exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;

(h) Examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above; and

(i) When put on notice of problems with the Company's business practices, operations, or internal controls, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

40. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Sage.

41. At all times relevant hereto, the Individual Defendants were the agents of each other and of Sage and were at all times acting within the course and scope of such agency.

42. Each of the Individual Defendants breached his or her fiduciary duties as alleged herein, both individually and in concert with the other Defendants.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

43. In committing the wrongful acts alleged herein, the Individual Defendants have engaged in, or aligned themselves with, a common course of conduct, acting in concert and conspiring with one another to further their misconduct. They caused the Company to conceal the true facts as outlined in this complaint. Additionally, the Individual Defendants aided, abetted, and/or assisted each other in breaching their respective duties.

44. The purpose and effect of the conspiracy, common enterprise, and/or common course of conduct was, among other things, to enable and conceal the Individual Defendants' violations of the law, including breaches of fiduciary duty and unjust enrichment.

45. The Individual Defendants carried out their conspiracy, common enterprise, and/or coordinated actions by causing the Company to deliberately, recklessly, or negligently conceal material facts, fail to correct those misrepresentations, and violate applicable laws.

46. To advance this plan, conspiracy, and course of conduct, the Individual Defendants, both collectively and individually, carried out the actions described herein. As these actions were executed under the Board's authority, each of the Individual Defendants, being directors of Sage, was a direct, essential, and significant participant in the conspiracy, joint enterprise, and/or

coordinated conduct alleged in this complaint.

47. Each of the Individual Defendants aided, abetted, and provided substantial assistance in the wrongdoings described herein. In providing such assistance, each Individual Defendant acted with actual or constructive knowledge of the primary misconduct, either directly participated in or significantly contributed to the commission of that wrongdoing, and was, or should have been, aware of their overall role in furthering the misconduct.

48. At all relevant times, each of the Individual Defendants acted as an agent of the other Defendants and of Sage, and at all times operated within the course and scope of that agency.

SAGE'S CODE OF BUSINESS CONDUCT AND ETHICS

49. Sage's Code of Business Conduct and Ethics (the "Code of Conduct" or the "Values Code") begins with a message from Defendant Greene which states the following, in pertinent part:

> At Sage, we take pride in making medicines that matter so people can get better sooner and stay better longer. We embrace this mission with the understanding that it requires us to live Our Values in the way that we do business. Our Values Code is designed to help guide Sageans in fulfilling this commitment. It serves as the basis for our guidelines, policies and processes, reflecting that Our Values must be lived in a way that is respectful to each other, reflects our commitment to integrity in the work we do for our stakeholders, and complies with applicable laws, regulations, and industry standards.

50. The Code of Conduct applies to "all Sageans, from the Board of Directors to every employee," and violations may lead to "remedial and disciplinary measures," including "re-training, oral or written reprimands, warnings, probation, suspension with or without pay, demotions, salary reductions, termination of employment or service, and restitution, among other measures."

51. In discussing the Company's values, the Code of Conduct states that "[i]t is the responsibility of every officer, employee, consultant, and other business partner of Sage and its

subsidiaries (individually and collectively, 'Sageans') to always act with honesty and integrity."

52. In a section titled "Quality and Patient Safety," the Code of Conduct states, in pertinent part:

> Our commitment to Improve Lives prioritizes those who rely on products, information, services, education, and insights that we provide. Sage follows an established Quality System to ensure the safe and compliant development, production, and testing of our products. Sage is committed to meeting all regulatory requirements and promoting a culture of improving quality on a continual basis.

53. In a section titled "Product Promotion," the Code of Conduct states, in pertinent part:

> The well-being of patients and their relationships with HCPs may be impacted by how we communicate about our products. We intend for our promotional discussions, information, and materials to be accurate and not misleading, and to comply with all applicable laws, regulations, and industry codes, including the PhRMA Code on Interactions with Healthcare Professionals and the European Federation of Pharmaceutical Industries and Associations ("EFPIA") HCP Code.
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> * * *
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> We are committed to truthful, non-misleading, and fair balanced information about our products consistent with applicable regulations and guidelines. We do not overstate the efficacy of our products or minimize or misrepresent related risks or safety information.

54. In a section titled "Pricing and Payer Interactions," the Code of Conduct states that "Sage seeks to sustain the support and confidence of all stakeholders in this process. We are committed to fulsome and transparent communication of relevant data consistent with applicable laws, regulations, and industry standards."

55. With respect to conflicts of interest, the Code of Conduct states, in pertinent part:

> We also recognize that being a Sagean is a commitment. It requires a willingness to prioritize Sage's objectives over certain personal opportunities. We expect Sageans to proactively inform their manager and Compliance if they, their immediate family, or a household member is involved in certain activities that may intersect with Sage's interests, so steps can be taken to avoid the opportunity for, or perception of, a conflict of interest, while maintaining the spirit of

encouragement for Sageans pursuing personal interests.

A potential conflict of interest occurs when personal, financial, or other outside interests might interfere with Sage's interests or with decision-making on behalf of Sage. Even the appearance of a conflict of interest can damage reputations. Sageans must never place personal, social, financial, or political interests above the interests of Sage.

56. In a section titled "Financial Reporting, Retention and Disclosure," the Code of Conduct states, in pertinent part:

As a public company, the integrity, reliability and accuracy of Sage's books, records, and accounts are fundamental to our continued success and shareholder trust. We keep detailed and accurate books and records that fairly represent the disposition of our assets and operational results.

Sageans must never falsify any company record or create false or misleading documentation. This includes financial statements, time sheets, bills, invoices, expense reports, payroll records, benefits records, performance evaluations, and other forms and data used at Sage.

Sage's public reports and documents must include fair, accurate, timely and understandable disclosure in all material respects. Sageans who are responsible for these filings and disclosures, including Sage's principal executive, financial, and accounting officers, must use reasonable judgement and perform their responsibilities honestly, ethically, and objectively in this regard.

Similarly, Sageans who have responsibility for accounting and financial reporting matters must ensure that our accounting records and reports reflect all transactions, assets, liabilities, revenues, and expenses accurately, fairly, and in reasonable detail. They must also ensure that such records and reports comply with applicable laws and standards, including the Generally Accepted Accounting Principles ("GAAP"), and do not contain any materially false or intentionally misleading entries.

Sage maintains and stores company records in compliance with legal, regulatory, contractual, and financial obligations and we maintain operational efficiency by allowing for the disposition of records that are no longer required to be maintained and are no longer needed for an ongoing business purpose.

57. In a section titled "Research and Development," the Code of Conduct states, in pertinent part:

Sage drives experimentation and data-driven development by being fearless and

bold in our approaches. We encourage Sageans to think differently because big problems need innovative solutions. These attributes inform our research and development programs. In conducting these programs, we hold Sageans to the highest ethical, scientific, and clinical standards. We comply with all applicable laws, regulations, and industry standards related to our research and development activities, including the International Conference on Harmonisation, Guidelines for Good Clinical Practice ("ICH GCP"), Good Laboratory Practice ("ICH GLP"), and the Declaration of Helsinki. We keep the well-being and safety of research participants front and center in our efforts, and we are dedicated to the accurate and transparent reporting of results.

SAGE'S AUDIT COMMITTEE CHARTER

58. Pursuant to Sage's Audit Committee Charter, the purposes of the Audit Committee are to:

- oversee the accounting and financial reporting processes of the Company and the audits of the Company's financial statements;
- establish expectations for, oversee, and evaluate the effectiveness of a compliance and ethics program that advances a culture of integrity and upholds the Company's Code of Business Conduct and Ethics (as amended and/or restated from time to time, the "Values Code");
- take, or recommend that the Board of Directors of the Company (the "Board") take, appropriate action to oversee the qualifications, independence and performance of the Company's independent auditors; and
- prepare the report required by the rules of the Securities and Exchange Commission (the "SEC") to be included in the Company's annual proxy statement.

59. In a subsection titled "Audited Financial Statements and Annual Audit," the Audit Committee Charter states:

- The Audit Committee shall review the overall audit plan (both internal and external) with the independent auditors and the members of management who are responsible for preparing the Company's financial statements, including the Company's principal accounting officer or principal financial officer.
- The Audit Committee shall review and discuss with management (including the Company's principal financial officer) and with the independent auditors the Company's annual audited financial statements, including (a) all critical accounting policies and practices used or to be used by the Company, (b) the

Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations" prior to the filing of the Company's Annual Report on Form 10-K, and (c) any significant financial reporting issues that have arisen in connection with the preparation of such audited financial statements.

- The Audit Committee must review:

  (i) any analyses prepared by management, the internal auditors, if any, and/or the independent auditors setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative generally accepted accounting principles, or GAAP, methods on the financial statements. The Audit Committee may consider the ramifications of the use of such alternative disclosures and treatments on the financial statements, and the treatment preferred by the independent auditors. The Audit Committee may also consider other material written communications between the registered public accounting firm and management, such as any management letter or schedule of unadjusted differences;

  (ii) major issues as to the adequacy of the Company's internal controls and any special audit steps adopted in light of material control deficiencies;

  (iii) major issues regarding accounting principles and procedures and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles; and

  (iv) the effects of regulatory and accounting initiatives, as well as off-balance sheet transactions and structures, on the financial statements of the Company.

- The Audit Committee shall review and discuss with the independent auditors (outside of the presence of management) how the independent auditors plan to handle their responsibilities under the Private Securities Litigation Reform Act of 1995, and request assurance from the independent auditors that Section 10A(b) of the Exchange Act has not been implicated.

- The Audit Committee shall review and discuss with the independent auditors any audit problems or difficulties and management's response thereto. This review shall include (1) any difficulties encountered by the independent auditors in the course of performing their audit work, including any restrictions on the scope of their activities or their access to information, (2) any significant disagreements with

management and (3) a discussion of the responsibilities, budget and staffing of the Company's internal audit function.

This review may also include:

(i) any accounting adjustments that were noted or proposed by the independent auditors but were "passed" (as immaterial or otherwise);

(ii) any communications between the audit team and the audit firm's national office regarding auditing or accounting issues presented by the engagement; and

(iii) any management or internal control letter issued, or proposed to be issued, by the independent auditors.

- The Audit Committee shall discuss with the independent auditors those matters brought to the attention of the Audit Committee by the independent auditors pursuant to Auditing Standard No. 1301, as amended and/or restated from time to time, or any successor standard ("AS 1301").

- The Audit Committee shall also review and discuss with the independent auditors the report required to be delivered by such auditors pursuant to Section 10A(k) of the Exchange Act.

- If brought to the attention of the Audit Committee, the Audit Committee shall discuss with the Chief Executive Officer and principal financial officer of the Company (1) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act, within the time periods specified in the SEC's rules and forms, and (2) any fraud involving management or other employees who have a significant role in the Company's internal control over financial reporting.

- Based on the Audit Committee's review and discussions (1) with management of the audited financial statements, (2) with the independent auditors of the matters required to be discussed by AS 1301, and (3) with the independent auditors concerning the independent auditor's independence, the Audit Committee shall make a recommendation to the Board as to whether the Company's audited financial statements should be included in the Company's Annual Report on Form 10-K for the last fiscal year.

- The Audit Committee shall prepare the Audit Committee report required by Item 407(d) of Regulation S-K of the Exchange Act (or any successor

provision) to be included in the Company's annual proxy statement.

60. In a subsection titled "Unaudited Quarterly Financial Statements," the Audit Committee states:

> The Audit Committee shall discuss with management and the independent auditors, prior to the filing of the Company's Quarterly Reports on Form 10-Q, (1) the Company's quarterly financial statements and the Company's related disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations," (2) such issues as may be brought to the Audit Committee's attention by the independent auditors pursuant to Auditing Standard No. 4105, as amended and/or restated from time to time, or any successor standard, and (3) any significant financial reporting issues that have arisen in connection with the preparation of such financial statements.

61. In a subsection titled "Earnings Press Releases," the Audit Committee states:

> The Audit Committee shall discuss the Company's earnings press releases, as well as financial information and earnings guidance provided to analysts and rating agencies, including, in general, the types of information to be disclosed and the types of presentations to be made (paying particular attention to the use of "pro forma" or "adjusted" non-GAAP information).

62. In a subsection titled "Risk Assessment and Management," the Audit Committee Charter states:

- The Audit Committee shall discuss the guidelines and policies that govern the process by which the Company's exposure to risk is assessed and managed by management.

- In connection with the Audit Committee's discussion of the Company's risk assessment and management guidelines, the Audit Committee may discuss or consider the Company's major financial and cybersecurity risk exposures and the steps that the Company's management has taken to monitor and control such exposures.

63. In a subsection titled "Compliance Program Oversight," the Audit Committee states, in pertinent part:

- The Audit Committee shall periodically review policies and procedures of the Company's compliance and ethics program and related plans for monitoring compliance with such policies and procedures.

- The Audit Committee shall review and discuss at least annually with the Company's Chief Compliance Officer the effectiveness of the Company's compliance and ethics program.

- The Audit Committee shall meet periodically with the Company's Chief Compliance Officer and the General Counsel to discuss and review compliance and legal matters that may have a material impact on the financial statements or the Company's policies and procedures and internal controls. The Audit Committee shall advise the entire Board of such discussions, as appropriate.

64. In a subsection titled "Legal and Regulatory Compliance," the Audit Committee Charter states, in pertinent part:

> The Audit Committee may discuss with management and the independent auditors, and review with the Board, the legal and regulatory requirements applicable to the Company and its subsidiaries and the Company's compliance with such requirements. After these discussions, the Audit Committee may, if it determines it to be appropriate, make recommendations to the Board with respect to the Company's policies and procedures regarding compliance with applicable laws and regulations.

SUBSTANTIVE ALLEGATIONS

Background

65. Sage is a biopharmaceutical company that develops therapies to treat neurological and psychiatric conditions, including major depressive disorder, postpartum depression, and other mood disorders.

66. Prior to the Relevant Period, the Company's primary product was Zulresso, a treatment for PPD which gained FDA approval in March 2019 and was launched in the U.S. in June 2019. By the start of the Relevant Period, Zulresso was the only drug that Sage had commercialized and brought to market.

67. Zulresso is administered intravenously over 60 hours in a certified and medically-supervised healthcare setting and requires a risk evaluation and mitigation strategy program related to excessive sedation and sudden loss of consciousness. Due to these requirements, the $34,000

per-course cost, and its narrow application, Zulresso has historically generated only limited revenue for the Company. In 2023, for instance, Sage reported just $10.5 million in net revenue from sales of Zulresso. Indeed, in its 2023 annual report, filed on Form 10-K with the SEC on February 14, 2024, Sage described some of the difficulties impacting the Company's ability to generate revenue from Zulresso:

> Our current commercial operations for ZULRESSO are limited to account management focused on geographies that have existing, active ZULRESSO treatment sites. We expect that the commercial availability of ZURZUVAE for women with PPD, our limited commercial efforts for ZULRESSO, and barriers to treatment with ZULRESSO will continue to substantially limit the revenue opportunity for ZULRESSO and the number of healthcare settings that are or become treatment sites for ZULRESSO.

68. Sage has historically funded its operations primarily through proceeds from sales of common stock and other securities transactions. From the Company's inception in 2010 through 2023, Sage received aggregate net proceeds of $2.8 billion from these transactions, but incurred net losses each year except for 2020. That year, Sage reported net income of $606.1 million related to revenue recognized under a collaboration and license agreement with Biogen, Inc. ("Biogen"), which did not involve the sale of any products to the public (the "Biogen Agreement"). The Biogen Agreement involved the two companies jointly developing zuranolone (SAGE-217), Sage's flagship drug designed for the treatment of MDD and PPD, and SAGE-324, designed for the treatment of essential tremor for sale in the U.S.

69. Pursuant to the Biogen Agreement, Biogen agreed to an upfront payment of $875 million, along with additional payments conditioned on the meeting of certain commercial and regulatory milestones in exchange for an equal share of profits and losses for sales of zuranolone and SAGE-324 in the U.S. and the right to sell the two drugs in most markets outside the U.S.

70. As part of the agreement, Biogen agreed to purchase $650 million of Sage common

stock, constituting 10.7% of the Company's total outstanding shares, at the end of 2020.

71. Further, on December 16, 2021 Company filed a shelf-registration statement, enabling Sage to issue shares at will, without incurring the expense or delay related to the filing of additional registration statements.

72. On November 7, 2023, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen"), pursuant to which Sage could sell shares of common stock through Cowen from time to time.

73. As demonstrated above, prior to and throughout the Relevant Period, Sage was heavily reliant on securities transactions to fund its operations, including substantial research and development costs. Accordingly, increasing and maintaining its stock price was critical to the Company's business. This provided an incentive for Company leadership to issue the false and misleading statements detailed below, to maintain an artificially inflated price of Sage stock.

74. In addition to zuranolone and SAGE-324, the Company was in the process of developing SAGE-718 for the treatment of various cognitive disorders. Prior to the Relevant Period, Sage was conducting clinical trials to evaluate the safety and efficacy of these three drugs.

75. Sage was evaluating zuranolone in the LANDSCAPE and NEST clinical development programs. The LANDSCAPE program included five clinical studies of MDD: MDD-201B, MOUNTAIN, SHORELINE, WATERFALL, and CORAL. The NEST program included two placebo-controlled studies for PPD: ROBIN and SKYLARK.

76. With respect to SAGE-324, the Company conducted the KINETIC study, a placebo-controlled Phase 2 trial to evaluate the safety and efficacy of the drug for use in the treatment of essential tremor in adults. In April 2021, the Company reported that this study met its primary endpoint, and Sage was planning to initiate the KINETIC 2 study in late-2021.

77. For SAGE-718, the Company was conducting the PARADIGM study for patients with Parkinson's Disease cognitive dysfunction and the LUMINARY study for patients with Alzheimer's Disease. SAGE-718 was further subject to the DIMENSION study, a double-blind placebo-controlled trial to evaluate the efficacy of the drug for use in the treatment of Huntington's Disease.

The FDA Denies Approval of Zuranolone for Use in the Treatment of MDD

78. Despite zuranolone's potential use for the treatment of MDD and PPD, the Company consistently represented that its most promising market was the treatment of MDD.

79. Prior to and throughout the Relevant Period, Sage emphasized the substantial and growing market for antidepressants. In 2020, the market for antidepressants was $14.93 billion, projected to grow to $18.29 billion by 2027.

80. The COVID-19 pandemic increased the need for effective treatments for MDD. As Defendant Greene explained during a November 15, 2021 conference, "[d]epression is rising at an ever-increasing rate. It was rising quickly with the COVID pandemic into a fourfold increase from pre-pandemic level. So if we had drugs that worked effectively, that would not be happening. We would not see dramatic rising of cases." Defendant Greene continued, highlighting that "[p]eople with depression have higher case[s] of COVID because it messes with their immune system. So medically, getting someone better, fast and keeping them better, medically is the right thing to do."

81. While the market for antidepressants as a whole is substantial, the market for treating PPD is relatively small, in part because there is a significantly smaller pool of potential patients. One report has estimated the size of the PPD market at roughly $800 million in 2021. Further, there are significant challenges associated with commercializing treatments for PPD. As explained by an April 10, 2024 article in *Biopharma Dive* titled "New postpartum depression drugs

are here. Diagnosis, treatment hurdles still stand in the way," clinical trials often exclude pregnant women out of fear for harming the fetus, and the window of time to test therapies is small.

82. For these reasons, market analysts and commentators understood that the most lucrative market for zuranolone was the treatment of MDD. Indeed, on November 27, 2020 *Reuters* reported that the impetus for the Biogen Agreement was "to jointly develop and sell a treatment for major depressive disorder" failing to mention at all the drug's potential use for the treatment of PPD.

83. The treatment of MDD is complicated due to the subjective nature of the disease. As there are no objective assessments to evaluate the severity and symptoms of MDD, clinicians use a variety of subjective assessments to ascertain patients' feelings and symptoms, including the Hamilton Depression Rating Scale ("HAM-D") and the Montgomery-Asberg Depression Rating Scale ("MADRS"). HAM-D demonstrates the severity of a patient's MDD with a score that considers a variety of symptoms, including mood, insomnia, anxiety, weight loss, and suicidal tendencies. HAM-D considers fewer symptoms than MADRS but is quicker to administer and is sensitive to change over time.

84. The treatment of MDD is further complicated by the prolonged nature of the condition. MDD is a chronic illness, and the recurrence rate of depressive episodes is 50% after the first episode, 70% after the second, and 90% after the third. Accordingly, in order to secure FDA approval of zuranolone for the treatment of MDD, Sage would have to demonstrate long-term efficacy of the drug.

85. The Division of Psychiatry Products in the Center for Drug Evaluation and Research at the FDA issued its most recent guidance for the development of pharmaceuticals intended to treat MDD in June 2018. The guidance, titled "Major Depressive Disorder: Developing

Drugs for Treatment," emphasizes the importance of a long-lasting and effective treatment, referred to as durability.

86. The FDA advises that "[e]fficacy generally should be demonstrated within 1 week for a rapid-acting antidepressant," but "[d]urability of [the] effect beyond the initial response should be characterized." Pursuant to the FDA's guidance, "[t]o demonstrate both early onset of action and durability of effect, a primary efficacy endpoint early in the course of treatment would be chosen, with continued observation of drug-placebo differences over time."

87. The FDA's guidance further details the importance of "maintenance treatment," explaining that "[b]ecause depression usually is a cyclical disease, maintenance studies of conventional antidepressants are actually assessments of the ability of the drug to reduce the rate of recurrence of depression. . . . Conventional drugs for treatment of MDD are often taken long-term (defined as continuous or intermittent use for at least 6 months), given that MDD is a chronic condition requiring ongoing management to reduce the rate of recurrence."

88. In addition to the FDA's emphasis on durable efficacy for drugs used in the treatment of MDD, the FDA's guidance emphasizes the importance of considering placebo response rates in clinical trials for MDD treatments, explaining that "[h]igh placebo response rates and small magnitude of treatment effect (relative to placebo) are of concern in most conventional antidepressant trials, which makes defining the active control effect and choosing a noninferiority margin difficult . . . high placebo response and dropout rates" are "commonly observed, sponsors should consider these factors in sample size calculations to ensure that the trial has sufficient statistical power to detect the anticipated treatment effect."

89. Accordingly, pharmaceutical companies understood that the FDA would not likely approve short-term treatments for MDD and would require a demonstration of long-lasting

efficacy and durability, compared to placebo. Indeed, when the FDA approved zuranolone for the treatment of PPD but not MDD, it revealed that it had specifically communicated these requirements in meetings with the Company before and during the Relevant Period:

> Prior to NDA submission, the Agency interacted with the Applicant in numerous Type B and C meetings on May 15, 2018; December 13, 2018; May 15, 2019; January 30, 2020; February 4, 2021; June 15, 2021; September 13, 2021; and January 19, 2022. At these meetings, the Agency communicated that in the context of the proposed novel 14-day treatment paradigm, [REDACTED] the Applicant would need (1) to demonstrate durability of effect in addition to the acute 14-day treatment effect, (2) to characterize [REDACTED] and (3) to ensure a long-term safety database comprised of an adequate number of subjects [REDACTED] at the highest dose proposed for marketing (i.e., 50 mg).

90. In approving zuranolone for the treatment of PPD, the FDA further revealed a correlation between zuranolone and an increased incidence of suicidal ideation in MDD patients during clinical trials, a correlation which was not present in PPD patients.

91. In contrast, Auvelity (sometimes referred to herein as "AXS-05"), a drug developed by Axsome Therapeutics, Inc. ("Axsome"), secured FDA approval for the treatment of MDD in August 2022, demonstrating fast-acting and durable efficacy with minor side effects. As Sage acknowledged in its public filings, Auvelity was a potential competitor to zuranolone. With knowledge that Auvelity secured FDA approval in August 2022, the Individual Defendants must have been aware that the FDA would not likely approve any other drug for the treatment of MDD, unless it demonstrated higher, or at least comparable, durability and safety than Auvelity.

92. Further, double-blind studies demonstrated effectiveness of Auvelity from week one through week six of treatment with statistical significance. Sage's WATERFALL and CORAL studies, by contrast, showed no statistically significant difference from placebo at Day 42 of treatment for zuranolone. Despite this, throughout the Relevant Period, the Individual Defendants failed to disclose the risk associated with Auvelity securing FDA approval and its demonstrated

superiority with respect to safety and durable efficacy relative to zuranolone in clinical trials. Specifically, the Individual Defendants failed to disclose that Auvelity's proven durability and safety would significantly impact both zuranolone's commercial prospects and its likelihood of securing FDA approval.

93. On August 4, 2023, Sage announced that the FDA had denied the approval of zuranolone for use in the treatment of MDD, questioning the efficacy of the drug and its safety for MDD patients, and granting approval for PPD only. On this news, the price of Sage stock declined precipitously. Further, in connection with the news, Sage announced that it would be forced to undergo a "strategic reorganization," which included a 40% reduction in the Company's workforce.

94. Over the course of the next year, the Company would reveal that its other two drugs in development were also suffering significant setbacks.

95. On April 17, 2024, the Company would reveal the results from its PRECEDENT study of SAGE-718, disclosing that the drug was no more effective than a placebo over the relevant period studied. As a result, the Company announced that it would no longer develop SAGE-718 for use in the treatment of Parkinson's Disease.

96. Then, on July 24, 2024, the Company revealed results from its Phase 2 KINETIC 2 study of SAGE-324, disclosing that, like SAGE-718, SAGE-324 was no more effective than a placebo over the relevant period studied. As a result, Sage announced that it was closing the open label study of SAGE-324 in essential tremor.

97. On September 26, 2024, the Company announced the termination of its collaboration with Biogen on the development of SAGE-324. Finally, on October 17, 2024, the Company announced another "strategic reorganization," whereby Sage would be terminating 33%

of its total workforce, including 55% of the research and development workforce. The reorganization further involved the departure of five senior executives, including Defendant Iguchi.

Materially False and Misleading Statements During the Relevant Period

98. On April 12, 2021, Sage issued a press release, filed on a current report on Form 8-K with the SEC, announcing results from the Phase 2 KINETIC study on the use of SAGE-324 for use in the treatment of essential tremor (the "April 12, 2021 Press Release"). The study assessed the efficacy, safety, and tolerability of a 60 mg dose of SAGE-324, administered once daily for 28 days to 69 patients with essential tremor with a two-week follow-up period, compared with a placebo. The dose could be down-titrated to 45 mg or 30 mg, which occurred in 62% of patients, if 60 mg was not well tolerated; and 38% of patients were discontinued. One purpose of the study was to determine the effect of SAGE-324 pursuant to the Essential Tremor Rating Assessment Scale ("TETRAS"), which measures the impact of essential tremor on the activities of daily living ("ADL"). In the April 12, 2021 Press Release, the Company represented that the study met its primary endpoint and SAGE-324 outperformed the placebo:

> The study (n=67 full analysis set) achieved its primary endpoint of a statistically significant reduction from baseline compared to placebo in The Essential Tremor Rating Assessment Scale (TETRAS) Performance Subscale Item 4 upper limb tremor score on Day 29 (P=0.049), which corresponded to a 36% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 compared to a 21% reduction in patients receiving placebo. Activities of daily living (ADL) scores showed a statistically significant correlation with upper limb tremor score at all timepoints. While not powered to fully examine TETRAS ADL, SAGE-324 was numerically superior to placebo at all time points.

99. The April 12, 2021 Press Release further reported that SAGE-324 demonstrated efficacy for use in the treatment of more severe tremor:

> In the KINETIC Study, patients (n=47) with a more severe tremor at baseline (at or above the median TETRAS Performance Subscale upper limb tremor Item 4 score

> of 12) who received SAGE-324, demonstrated a statistically significant reduction (P=0.007) from baseline in TETRAS Performance Subscale Item 4 upper limb tremor score compared to placebo at Day 29, corresponding to a 41% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 compared to an 18% reduction for placebo. Study patients were not taking other medications for ET during the 28-day treatment period.

100. The April 12, 2021 Press Release quoted Defendant Greene as stating:

> In the design of the KINETIC Study, we set a high bar and believe we exceeded it. SAGE-324 met the primary endpoint in the trial and demonstrated a safety profile generally consistent with previously reported data. The strong correlation observed in this study between TETRAS performance scale—measuring reduction of upper limb tremor, a disabling symptom experienced by more than 90% of people suffering from essential tremor—and improvement on the ADL score provides suggestive evidence that these findings have the potential to be truly impactful for people with essential tremor.

101. The same day, the Company hosted an analyst conference call to discuss the topline results of the Phase 2 KINETIC study of SAGE-324 (the "April 12, 2021 Analyst Call"). In his opening remarks, Defendant Greene highlighted the purported efficacy of SAGE-324, stating that "as we've been saying for some time, we were looking for a big effect, in the range of 30% to 50% sustained reduction in tremor amplitude from baseline." Defendant Greene continued, adding that Sage was "looking for the high end of the dose range [to] have the meaningful effect. . . . This was the high bar, and we believe we exceeded it." Defendant Greene further stated:

> First of all, the study achieved its primary endpoint with SAGE-324 demonstrating a statistically significant reduction from baseline in the TETRAS Item 4 upper limb tremor score at day 29 in the total study population compared to placebo or the ITT analysis, which corresponds to a 36% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 versus the 21% reduction in patients receiving placebo. And the safety profile was generally consistent with previously reported data from SAGE-324.
>
> Other highlights from the study to point out. Patients with a more severe tremor baseline, those representing the moderate-to-severe patient population, demonstrated a statistically significant reduction from baseline in the TETRAS Item 4 upper limb tremor score at day 28, which corresponded to a 41% reduction in upper limb tremor amplitude compared to an 18% reduction for placebo. We believe patients with more severe tumor, that is TETRAS score of greater than 12,

> represent the majority of ET patients getting diagnosed and seeking treatment today.

102. Despite acknowledging that the study was unable to fully examine the impact of essential tremor on daily living activities, Defendant Greene nonetheless represented that the Company had a positive outlook with respect to the development of SAGE-324:

> Importantly, the activities of daily living, or ADL scores, showed a statistically significant correlation with upper limb tremor scores at all time points. Now while not powered to fully examine TETRAS ADL, SAGE-324 was numerically superior to placebo at all time points during the study, demonstrating the clinically meaningful nature of these data and the importance to ET patients.
>
> So hitting statistical significance in the primary endpoint, achieving clinically meaningful reductions in tremor amplitude, seeing the ADL tremor correlation all with an AE profile that was in line with our expectations for the 60-milligram dose is [an] encouraging and exciting outcome for this Phase II trial. These data reinforce our belief that the pharmacologic characteristics of SAGE-324 are well suited for development opportunities in essential tremor and possibly other indications. With these new data, we'll work with our collaboration partners at Biogen to optimize next steps for the continued development of SAGE-324 in essential tremor.

103. Later during the April 12, 2021 Analyst Call, in response to an analyst question, Defendant Greene represented that SAGE-324 demonstrated high efficacy, stating that "[w]hat we are looking for is a 30% to 50% reduction in tremor amplitude over time. We saw that."

104. Defendant Kanes reiterated that the study yielded positive results, stating that SAGE-324 "met its primary endpoint, a significant reduction in TETRAS Item 4 upper limb tremor score from baseline at day 29," constituting a 36% reduction from baseline compares to a 21% reduction for the placebo. Defendant Kanes added that, for more severe tremor, the study demonstrated a 41% reduction from baseline at Day 29 compared to 18% for the placebo.

105. Defendant Kanes further stated that "activities of daily living scores showed a statistically significant correlation with upper limb tremor scores at all time points," explaining that the result was "an important consideration" "[f]rom a clinical point of view." Defendant Kanes

represented that he was "highly encouraged" by the results, as "SAGE-324 performed as we anticipated." Defendant Kanes further claimed that "the important point here is that now we know that we have a drug which shows the effect, the effect didn't wear out. It didn't wear off or tachyphylaxis over the course. . . . Suffice it to say that these are truly clinically meaningful results."

106. In response to a question regarding "how the [FDA] might be weighing the significance of improvements on functional endpoints versus straight tremor reductions," Defendant Greene stated that "at every time point, activities of daily living were superior for drug versus placebo [and that] gives us tremendous flexibility as we negotiate with the agency." Defendant Greene further represented that the "statistically significant correlation . . . again, gives us tremendous optionality as we work with regulators on what's the most important and on what's most important to patients."

107. Defendant Doherty affirmed that the Company was optimistic about the results of the test, stating that "it's really very, very interesting and very encouraging that we're seeing a good correlation across response to the primary endpoint, the TETRAS scale as well as response to the ADL." Later during the April 12, 2021 Investor Call, Defendant Doherty stated that "the placebo response is more or less in line with what we are hearing from KOLs [key opinion leaders] and others working in the space."

108. At the end of the April 12, 2021 Analyst Call, Defendant Kanes reiterated that the study demonstrated SAGE-324's efficacy:

> For us, this is, first and foremost, a scientific confirmation that dosing over the course of a month with this mechanism has true differences. Those differences are maintained over time that the mechanism that we've seen repeatedly with multiple drugs, related drugs in this class does holds up into the most, I would say, rigorous scrutiny in a randomized, placebo-controlled trial. And that gives us great confidence to move forward.

109. The statements identified above, issued by the Individual Defendants on April 12, 2021, were materially false and misleading and omitted to state material adverse facts necessary to make the statements not misleading because they failed to disclose that: (i) the FDA was generally hesitant to use TETRAS scale as an endpoint to evaluate the efficacy of drugs for use in the treatment of essential tremor; (ii) accordingly, promoting the use of the TETRAS scale as a primary endpoint, and touting the purportedly strong results demonstrated from SAGE-324's study was misleading; (iii) it was therefore misleading to highlight the "strong correlation . . . between [the] TETRAS performance scale . . . and improvement on the ADL score," and to claim that "now we know that we have a drug which shows . . . effects" that "didn't wear off or tachyphylaxis," without cautioning investors with respect to the primary endpoint used; and (iv) the Individual Defendants generally overstated the study's results, including by claiming that SAGE-324 dosing "maintained over time that the mechanism that we've seen repeatedly with multiple drugs, related drugs in this class does holds up into the most . . . rigorous scrutiny."

110. On April 29, 2021, Sage filed a proxy statement on Form DEF 14A with the SEC (the "2021 Proxy"), soliciting shareholder approval for, *inter alia*, the re-election of Defendants Barrett, Germano, and Paul to serve for another three-year term on the Company's Board and the compensation of certain of the Company's executive officers, including Defendants Greene, Jonas, Iguchi, and Robichaud.

111. With respect to zuranolone, the 2021 Proxy highlighted its purported durability, reporting that "approximately 70% of patients successfully treated with zuranolone 30 mg in the first treatment cycle needed two or fewer treatment courses over one year."

112. With respect to the KINETIC study of SAGE-324, the 2021 Proxy reported that the study "had achieved its primary endpoint."

113. With respect to the Company's internal controls and legal and regulatory compliance the 2021 Proxy stated that "the Audit Committee operates under a written charter approved by the Board of Directors, which provides that its responsibilities include the oversight of the quality of our financial reports and other financial information and our compliance with legal and regulatory requirements" and "reviewing with management and our independent registered public accounting firm the adequacy of our internal controls over financial reporting."

114. With respect to the Company's risk assessment and risk management functions, the 2021 Proxy stated:

> Our Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board of Directors performs this oversight role by using several different levels of review. In connection with its reviews of the operations and corporate functions of our company, our Board of Directors addresses the primary risks associated with those operations and corporate functions. In addition, our Board of Directors reviews the risks associated with our company's business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.
>
> Each of the committees of our Board of Directors also oversees the management of our risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Financial Officer provides reports to the Audit Committee, and is responsible for identifying, evaluating and implementing financial risk management controls and methodologies to address any identified risks. In connection with its risk management role, our Audit Committee meets privately with representatives from our independent registered public accounting firm, and privately with our Chief Financial Officer. The Audit Committee evaluates from time to time the processes by which our exposure to risk is assessed and managed by management.

115. On May 4, 2021, Sage issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's first quarter 2021 financial results (the "1Q21 Press Release"). The same day, Sage filed a quarterly report on Form 10-Q with the SEC for its first quarter of 2021 (the "1Q21 10-Q") and held a related earnings call (the "1Q21 Earnings Call").

116. With respect to Axsome and Auvelity, the 1Q21 10-Q broadly stated that "[i]n April

2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which received Breakthrough Therapy designation for MDD in March 2019."

117. The 1Q21 Press Release highlighted the purportedly positive results of clinical trials for zuranolone, SAGE-324, and SAGE-718 and quoted Defendant Greene as stating that "the progress we've made so far this year sets us up for near-, medium- and long-term value creation opportunities as we further advance our deep organic pipeline."

118. With respect to results of the SHORELINE study, conducted to assess zuranolone's "safety and tolerability . . . in adults for up to one year," the 1Q21 Press Release reported that, "[a]fter the initial 2-week zuranolone treatment, more than 70% of patients who received 30 mg and 80% of patients who received 50 mg achieved positive response at Day 15." The 1Q21 Press Release explained that 70% of patients who received 30 mg "required at most one additional zuranolone treatment during the 12-month study," consisting of 210 of 489 patients (or 42.9%) who "used only the single initial zuranolone course" and 125 (or 25.6%) who "used a total of two courses." Of the 199 patients who received 50 mg, "43.2% achieved remission after the initial 2-week treatment period."

119. With respect to results of the KINETIC study, conducted to assess the "efficacy, safety, and tolerability of SAGE-324 60 mg in patients" with essential tremor aged 18 to 80 years old, the 1Q21 Press Release reported that "the daily dose could be down-titrated to 45 mg or 30 mg if 60 mg was not well tolerated," which "occurred in 62% of patients," while treatment was discontinued for 38% of patients. The 1Q21 Press Release further reported that "ADL scores showed a statistically significant correlation with upper limb tremor score" and that the study demonstrated that the drug was "numerically superior" to the placebo at all time points.

120. The 1Q21 Press Release further reported the results of the Phase 2a open-label PARADIGM study, conducted to assess the efficacy of SAGE-718 on eight patients, aged 50 to 75 years old with mild cognitive impairment caused by Parkinson's Disease, who received 3 mg daily for two weeks. The 1Q21 Release explained that "[p]atients showed performance improvements from baseline on multiple tests in the cognitive domain of executive function during the 14 days of treatment" and that "[e]merging signals on several measures also suggested improved performance from baseline on additional cognitive tests in the domains of learning and memory."

121. During the 1Q21 Earnings Call, Defendant Greene opened by reporting that, for zuranolone, "[t]he 30-milligram showed that approximately 70% of participants had a positive response to an initial 2-week treatment and required at most 1 additional zuranolone treatment during the 12-month study period," and that "more than 70% of patients who received 30 milligrams and 80% of patients who received 50 milligrams achieved positive response at day 15." With respect to SAGE-324, Defendant Greene stated that Sage's objective was to achieve "a reduction in tremor amplitude of 30% to 50% that was sustained for the full study period" in the KINETIC study, explaining, "[i]n other words, no loss of effect or tachyphylaxis." According to Defendant Greene, the drug "achieved our objectives and more." With respect to SAGE-718, Defendant Greene explained that "the interim data cut" from the PARADIGM study "showed patients demonstrated improved performance from baseline on multiple tests of executive function over 14 days of treatment."

122. Also during the 1Q21 Earnings Call, Defendant Kanes touted the purportedly "great progress across all 3 franchises to date," reporting that, with respect to zuranolone, "[i]n the 30-milligram cohort at day 15, the mean change from baseline was 15.2 points and 73.5% of patients

achieved response. And 40% achieved remission as measured by a HAM-D score of less than or equal to 7. . . . In the 50-milligram cohort at day 15 of the initial treatment course, the mean HAM-D change from baseline was 16. 80.5% of patients achieved response and 43.2% achieved remission."

123. Later during the 1Q21 Earnings Call, an analyst asked a question regarding "what is acceptable sedation, and what is acceptable somnolence." Specifically, the analyst asked if "there [is] a threshold, a written threshold in the public domain by [the] FDA on what might complicate actual approval either on sedation or somnolence." In response, Defendant Greene highlighted the efficacy of zuranolone at treating MDD relative to other approved drugs, stating that "to date, the profile we've seen is extraordinarily consistent," with "rapid onset of action in 3 to 4 days, patients report they're feeling better," as well as "remarkable efficacy [in] 2 weeks, both 30 and 50 [mg], with most patients requiring only 1 or 2, 2-week doses in the entire year." Defendant Greene continued, stating that, "to be clear, if we hit the primary endpoint, given the different benefit risk of zuranolone, over 35 years' worth of antidepressants, we have a very important medicine in the [Company's] LANDSCAPE [drug development program]." Defendant Kanes elaborated that "somnolence is something that is often desirable for patients with depression" and that this desirable side effect led to the "very low dropout rate from our clinical trials." Defendant Kanes reiterated Defendant Greene's point that, with respect to zuranolone, "the numbers that we're reporting are actually comparable, if not better, than many drugs that are used right now to treat depression" and stating that "reports that we have for either somnolence, sedation and so forth, are well within the parameters of drugs that are approved for the treatment of depression, even standard antidepressants."

124. Later during the 1Q21 Earnings Call, an analyst asked for "information available

at the top line" from the WATERFALL study for zuranolone's "durability . . . maybe longer term, say, 42, things of that nature . . . how important . . . based on your doctor feedback" is "longer durability of response for these acute treatment regimes?" In response, Defendant Greene stated that "[t]here's nothing out there that gets patients better, faster and keeps them better," but acknowledged that "we're looking at all the secondary endpoints. Defendant Greene added, stating that, "[f]or day 42, what we're looking for is consistency of effect in the drug arm, not necessarily versus placebo."

125. Then, an analyst explained that "a practice mentioned they couldn't claim MDD treatment if they only treat patients for 15 days" "[s]o they also look at the day 28 data for their MDD drug candidate." The analyst then asked: (i) "how important is that [secondary endpoint] day 42 data for [the] zuranolone filing"; and (ii) "how did [the] FDA view the open-label SHORELINE study and supporting evidence for the durability of zuranolone?" In response, Defendants Greene and Kanes highlighted zuranolone's primary endpoint of efficacy at Day 15 and "unique" profile.

126. An analyst then asked a question regarding zuranolone's prospects for securing FDA approval: "If WATERFALL and CORAL were to fail, but the Phase III postpartum study were to succeed, would you launch this drug in PPD, and then kind of figure everything else out later, or would you wait?" In response, Defendant Greene stated:

> [W]e are highly encouraged by the upcoming data readouts. We sat down with the agency and mapped out 3 unique approaches, 3 unique different ways to potentially get approval to an MDD, as you've highlighted, and 1 in PPD. And we believe that 1 of those Phase III needs to be positive for us to have a drug on the market.
>
> So we're very enthusiastic about all 3 approaches and believe that as you see with many drugs, we need 1 positive Phase III here. And that's an agreement with the agency. Yes, we scenario plan with Biogen at a very high level, but not in any detail.

127. The statements identified above, issued by the Individual Defendants on May 4,

2021, were materially false and misleading and omitted to state material adverse facts necessary to make the statements not misleading because they failed to disclose that: (i) the Individual Defendants understated the risk posed by Auvelity to the Company's ability to secure FDA approval for zuranolone; (ii) the FDA was unlikely to approve both Auvelity and zuranolone in succession, particularly due to Auvelity's superior results in clinical studies; (iii) the Individual Defendants understated the impact that FDA approval of Auvelity would have on zuranolone's potential market share and commercial prospects; (iv) the demonstrated efficacy of zuranolone for the treatment of MDD was overstated, and it was misleading to represent that "the numbers [Sage is] reporting are actually comparable, if not better, than many drugs that are used right now to treat depression"; (v) the demonstrated durability of zuranolone was overstated; (vi) the efficacy and durability of SAGE-324 was overstated; and (vii) the adverse safety effects related to the use of zuranolone were significantly understated.

128. On June 15, 2021, Sage issued a press release, filed on a current report on Form 8-K with the SEC, announcing results from the double-blind, placebo-controlled pivotal Phase 3 WATERFALL study on the efficacy and safety of zuranolone for adults with MDD (the "June 15, 2021 Press Release"). The study evaluated 543 patients with MDD. Each patient received 50 mg of zuranolone or placebo nightly for 14 days, with about 90% of patients in each group completing the study. The June 15, 2021 Press Release reported that the study met its primary endpoint, "showing statistically significant improvement in depressive symptoms compared with placebo at Day 15 as assessed by the 17-item Hamilton Rating Scale for Depression (HAMD-17) total score." The June 15, 2021 Press Release further represented that "[p]atients with a response at Day 15 in the zuranolone group retained on average 86.1% of their HAMD-17 improvement at Day 42 (4 weeks after dosing ended)," explaining that, "[w]hile not statistically significant, a numerical

advantage in favor of zuranolone was demonstrated at Day 42."

129. The same day, Sage hosted an analyst conference call to discuss results from the WATERFALL study (the "June 15, 2021 Analyst Call"). During his opening remarks, Defendant Greene stated that zuranolone met its primary endpoint, "demonstrating a statistically significant reduction in HAM-D scores at day 15 at the end of the 14- day dosing period." Defendant Greene further reported that "patients who responded to zuranolone at day 15 retained more than 85% of their improvement out to the last time point in the study, day 42. And just to be clear, that's 4 weeks after the last dose of [the] drug." Defendant Greene emphasized zuranolone's purported durability in treating MDD, stating that "rapid onset of activity . . . after the second dose, as measured by day 3 . . . more than 70% patients receiving a 30-milligram dose of zuranolone needed only 1 or 2, 2-week treatments over the course of a year to maintain wellness."

130. Defendant Greene claimed that communications with the FDA underscored zuranolone's promising prospects, stating that "we sat down with the agency and mapped out 3 distinct Phase IIIs, any of which, if positive, was a fileable event. We believe that that's what we have here with WATERFALL."

131. Also during the June 15, 2021 Analyst Call, Defendant Kanes highlighted zuranolone's purported advantages over competitors with respect to durability in the treatment of MDD, stating that "current treatment options require chronic dosing, may take up to 4 to 6 weeks to show an effect, if any, and often cause troubling side effects."

132. An analyst then asked the following question:

> I wanted to talk about regulatory, I guess, and I hope you don't mind if it's [a] two-part question. I guess for one, how would you characterize your confidence level that this is truly a positive study from a regulatory perspective, and that a lack of delta, small waning of effect of the drug at day 42 doesn't matter regulatory-wise? And then the second thing on regulatory, maybe you could just comment on what your base case is for how much safety data you'll need in terms of retreatment and

> long-term follow-up, and whether or not you have that right now or you're likely to need materially.

133. In response, Defendant Greene reiterated that "we set out at the beginning of the year guiding that after meeting with the FDA, we designed 3 unique Phase IIIs that presented 3 unique opportunities for positive readouts, any of which, if hit, were a fileable outcome." Defendant Greene referenced the WATERFALL study's "very statistically significant p-value at day 15," adding that "we believe that we have a fileable data." Later during the call, Defendant Greene reiterated the idea that the Company could secure FDA approval based on the results from the WATERFALL study alone, even if results from the ongoing CORAL study were negative:

> [W]e have 3 unique Phase IIIs. Any one of which, if positive, is fileable. So positive CORAL would be great, but it's not needed for approval. We believe that what we see in WATERFALL is what we need for a drug to be approved.

134. Defendant Kanes further highlighted the drug's purported durability, or "maintenance of efficacy," stating:

> [W]ith regard to regulatory, the way that we're thinking about maintenance of efficacy, we've had this question before with ZULRESSO, what's important here is stability. And we certainly have demonstrated that across the entire program with more than 85% of patients maintaining benefit. So overall, we're looking forward to having those discussions with the FDA. But this is clearly fileable, and as Barry said, we're looking to think about the most efficient way to do that.

135. An analyst then questioned what physicians would consider in "decid[ing] whether to prescribe the drug," asking if they would "merely look at the delta versus placebo at day 15 and day 42[.]" In response, Defendant Greene explained that, "[o]bviously, we're thrilled with these data," adding that "physicians will reach for zuranolone either alone or concomitant with another antidepressant, which doesn't necessarily help get them out of the depressive symptoms but can help them, once better, stay well as we've seen with zuranolone." Defendant Kanes then touted zuranolone's purported ability to "treat patients quickly," as well as its durability:

> [A]t the end of the day, we know that in clinical trials, people talk about placebo and delta from placebo. For clinical treatment, it's how quickly do patients get better, how much better do they do and what happens after they stop therapy. And what's unique about this and absolutely different from everything that's out there is the ability to treat patients quickly, a 2-week course of therapy, and then know that if they need additional retreatment as we've seen in SHORELINE, they'll have reliable response again. That's something very, very different.

136. Later during the June 15, 2021 Analyst Call, Defendant Greene explained that "the reduction in HAM-D scores in the WATERFALL are clinically meaningful. . . . And just to emphasize, what's important here again is that patients got better rapidly and stayed better longer with maintenance of effect out to day 42, and that's what matters most to patients." Defendant Kanes then represented that "[t]he consistency that we've seen in terms of the overall benefit for patients on zuranolone has been rock solid since our first study." Defendant Kanes then stated the following with respect to the delta from placebo:

> And so the delta from placebo, that's driven entirely by the variability that we see in placebo. And that's a constant challenge within depression trials. It's one of the reasons why we emphasize what it is that the drug does as opposed to trying to war game out what that delta from placebo is.
>
> So at the end of the day, as we said, the large drops in terms of symptoms as well as the maintenance of efficacy is what really matters to patients. And from a physician and from patient perspective, those are the things that are absolutely critical for when they would choose to use this and for which patients.

137. Defendant Doherty agreed that "placebo response does vary," noting that zuranolone demonstrated "rapid response as early as day 3" that "maintained out through time," while "the placebo response" occurred "through day 15." Later during the June 15, 2021 Analyst Call, Defendant Kanes similarly responded to a question regarding the "maintained response rate for placebo," failing to address whether the placebo response undermined zuranolone's trial results:

> So the placebo was maintained. I mean we see placebo across all of our trials. And that's why our—obviously, we didn't separate from placebo at day 42. A little less

> relevant because if you look in the real world, the placebo responses aren't what and what no treatment really refers to. And that's one of the challenges in this field, but really, the important part here is day 15 in the primary endpoint.

138. With respect to "the secondary endpoints, relapse and remission rates," Defendant Doherty explained during the June 15, 2021 Analyst Call that "response and remission rates are really consistent with the pooled response and remission rates across the placebo-controlled Landscape and Nest studies, including both MDD and PPD. . . . "The key point is that patients are getting better fast, and they're maintaining that improvement out through the study."

139. Defendant Kanes then responded to a question regarding durability by stating that "about 70% of patients require no more than 1 additional treatment in a year using standard diagnostic criteria," "[s]o that's really better to understand what the rate of retreatment might be than rather—rather than at 30 days." Defendant Kanes continued, stating:

> So we looked for where our triggers of true MDD, where patients actually have recurrence of symptoms. And as I said, 50% of patients didn't require any additional therapy over the course of the year, and 70% required—excuse me, 70—the additional 20% only required 1 additional treatment. So a really durable response and an important option for patients if approved.

140. Defendant Greene added:

> [J]ust to highlight, what's remarkable there, again, 70% of patients, that was a 30-milligram group, only required 1 or 2, 2-week courses. So that's 4 weeks of drug out of 52 weeks, being drug-free for the rest of the time. That's important to patients. And what's really critical and often missed here, not by physicians per se, is that they know they're off drug, and yet they're still maintaining that benefit. It's almost a reverse placebo effect, if you will.

141. Lastly, Defendant Greene highlighted zuranolone's "durable effects out to day 42," with Defendant Kanes adding that the "data continue to support what we've known about this drug for quite some time: rapid, very large effects and durable effects that we can use to treat patients episodically." Defendant Kanes further claimed that "the metric of just trying to understand difference from placebo, it could be misleading. . . . What you need to look at is how large an

effect was there for patients, would they notice it. . . . Those large effects are what's different. Placebo will do what placebo does, but we're seeing some very dramatic and very different effects over a very short period of time. And it just bears repeating that we're talking about these effects being durable after only 2 weeks of therapy."

142. The statements identified above, issued by the Individual Defendants on June 15, 2021, were materially false and misleading and omitted to state material adverse facts necessary to make the statements not misleading because they failed to disclose that: (i) representations that WATERFALL met its primary endpoint of "showing statistically significant improvement in depressive symptoms compared with placebo at Day 15," and "a numerical advantage in favor of zuranolone" at Day 42 overstated the significance of demonstrating short-term improvement in symptoms of depression; (ii) the Individual Defendants overstated the durability of zuranolone; (iii) the Individual Defendants downplayed the significance of the placebo effects in the study, which undermined the purportedly positive results achieved for zuranolone.

143. The revelations that zuranolone demonstrated only a purported "numerical advantage," and not a statistically significant response, in the WATERFALL study at Day 42 caused the price of Sage stock to decline significantly. Specifically, the price of Sage stock declined 19.3%, from a close of $72.86 per share on June 14, 2021 to a close of $58.80 per share on June 15, 2021. Despite this, the price of Sage stock remained artificially inflated as the Individual Defendants continued to issue materially false and misleading statements, overstating zuranolone's efficacy and durability and the likelihood of the drug securing FDA approval for use in the treatment of MDD.

144. On July 13, 2021, Defendants Greene and Kanes participated at the Cowen Psychedelics & Novel Mechanisms in Neuropsychiatry Summit on behalf of Sage. At the summit,

Defendant Kanes touted the purported durability of zuranolone:

> And in study after study, we've been able to demonstrate that we're improving those core symptoms. And we're in a durable way, long after the patients have stopped taking medication. And we saw that in the WATERFALL study, perhaps most dramatically in our SHORELINE trial, which is where patients were treated for 2 weeks at a time, and we've seen that greater than 70% of patients needed no more than 2 treatments or 2 14-day course of treatments in a year. So really long, durable effects on depression, which we think is transformative for patients.

145. Defendants Kanes and Greene continued to minimize the significance of the placebo effect demonstrated in the WATERFALL study. In response to a question regarding "how [we should] be thinking . . . of the magnitude of the placebo effect that we saw" in the WATERFALL study, Defendant Greene claimed that "the totality of the data" confirmed that the drug worked rapidly, explaining that a patient "might only need 2 or 4 weeks of therapy in the course of the year." Defendant Greene further explained that the "industry has been trying to figure out placebo effect on depression studies for a couple of decades, 35 to 50 years," adding that the Company had sufficient data to secure FDA approval:

> [T]hat's a big challenge. What's important—and obviously, when you conduct the clinical studies, you want to minimize placebo so that you tease out the drug effect. We've done that. As early as January, Steve and I were saying to everybody, "All we're looking for is a statistically significant result at day 15 and no surprise on adverse event." We've got that along with the other positive study, the totality data, we believe we have an approvable package, and we stand on that today.

146. Defendant Greene further stated that "even as robust [as] the placebo effect was, the drug effect was clear and in the range and held out to Day 42." In response to a question regarding "the sort of decline of effect at day 42" and whether that "means there is no discernible effect at that time point," Defendant Kanes stated:

> What we're referring to here is something that's really important conceptually, which is rather than thinking about delta from placebo at day 42, we look to see whether patients maintain their benefit. And what we said is that when you look at the overall change from baseline at the end of treatment, you carry that out through day 42 and you look at whether or not those numbers are the same.

> So it's 2 things we learned. One, those numbers are not statistically different. So we know that patients aren't having statistically significant changes in their overall change from baseline. The other is that if you just use the raw numbers, it's 87% of the benefit that they had seen at day 15.

147. The statements identified above, issued by the Individual Defendants on July 13, 2021, were materially false and misleading and omitted to state material adverse facts necessary to make the statements not misleading because they failed to disclose that: (i) the reported efficacy and durability of zuranolone was overstated; and (ii) the Individual Defendants continued to downplay the significance of the placebo effect demonstrated in the zuranolone study.

148. On August 3, 2021, Sage issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's second quarter 2021 financial results (the "2Q21 Press Release"). The same day, Sage filed a quarterly report on Form 10-Q with the SEC for its second quarter of 2021 (the "2Q21 10-Q") and held a related earnings call (the "2Q21 Earnings Call").

149. The 2Q21 Press Release repeated the previously disclosed topline results of the WATERFALL study, stating that the study "met its primary endpoint demonstrating statistically significant and clinically meaningful improvement in depressive symptoms compared with placebo at Day 15" on the HAMD-17 scale, adding that patients who responded to the drug on Day 15 "retained on average 86% of their HAMD-17 improvement at Day 42 (4 weeks after dosing ended)."

150. The 2Q21 Release revealed that the Company was "formally terminating the REDWOOD and RAINFOREST Studies, which were suspended in the first quarter of 2020," explaining that, "[a]fter discussions with the FDA, Sage does not believe that these studies will be required for a potential NDA submission."

151. The 2Q21 Release further revealed that, in the KINETIC study, "SAGE-324 demonstrated a statistically significant reduction from baseline in the TETRAS Item 4 upper limb tremor score at Day 29 . . . [as] compared to placebo" and "a statistically significant correlation between TETRAS tremor score and [ADL]." The 2Q21 Release announced that the Company was conducting the PARADIGM and LUMINARY studies for SAGE-718.

152. During the 2Q21 Earnings Call, Defendant Green opened by reiterating that the Company "saw a clear maintenance of effect through day 42, 4 weeks after treatment was stopped . . . we believe we have the efficacy data in hand to file the first NDA for zuranolone." Defendant Greene further elaborated with respect to the Company's decision to terminate the REDWOOD and RAINFOREST studies:

> As you may recall, REDWOOD was designed to study fixed schedule intermediary dosing of zuranolone throughout the course of the year. We believe data from the SHORELINE Study address this question. [Because] RAINFOREST was designed to investigate the efficacy and safety of zuranolone in comorbid MDD and insomnia, while zuranolone has consistently improved sleep across clinical studies as measured by sleep component of the HAM-D scale, we do not believe RAINFOREST is required for initial filing.

153. Defendant Kanes then referenced the WATERFALL study and reiterated that "patients who responded to zuranolone after 2 weeks of treatment retained on average more than 85% of their improvement through the end of the trial"—"a full 30 days after the last does of mediation with the majority of these patients maintaining most, if not all, of the improvement." Defendant Kanes repeated the sentiment that "the data we've generated to date" and "ongoing pharmacology studies" were sufficient for "the regulatory NDA filing pathway."

154. Defendant Kanes similarly stated that in the CORAL study, "we expect to see [a] consistent efficacy profile supporting the differentiated benefit/risk of zuranolone in this trial, including rapid onset of effect" but that "[t]he positive results from the WATERFALL Study, we

believe, have sufficient efficacy data to support our first FDA filing for zuranolone."

155. In response to a question regarding whether CORAL would be necessary for zuranolone to secure FDA approval to treat MDD and whether "the FDA had indicated that SHORELINE would provide sufficient retreatment data for the [NDA] filing" in view of the "decision to terminate REDWOOD and RAINFOREST," Defendant Greene indicated that the Company is "in an ongoing dialogue" and can "confirm REDWOOD and RAINFOREST would not be required for this filing" and that data from SHORELINE are sufficient "to provide the retreatment evidence."

156. Defendant Greene further stated that zuranolone was a "2-week therapy" for treating MDD and that "most of the improvement happens within the first week," with incremental improvements "[b]y the end of 2 weeks" and "somewhere between 40% and 50% remission . . . the time limited aspect of this is what got the FDA's attention [and] is why we have a breakthrough [designation] in the first place."

157. The statements identified above, issued by the Individual Defendants on August 3, 2021, were materially false and misleading and omitted to state material adverse facts necessary to make the statements not misleading because references to non-public interactions with the FDA misleadingly instilled confidence in investors regarding the Company's prospects for securing approval for its drugs. Specifically, indications that the Company already had sufficient data to secure FDA approval, including that "[t]he positive results from the WATERFALL Study, we believe, have sufficient efficacy data to support our first FDA filing for zuranolone" were materially false and misleading and served to artificially inflate the price of Sage stock.

158. On August 11, 2021, Defendant Greene participated at the Canaccord Genuity Growth Conference on behalf of Sage. At the conference, Defendant Greene characterized the

host's suggestion that zuranolone exhibited similar effectiveness to placebo at Day 42 as "a big misinterpretation" of the "the WATERFALL study for day 42," explaining that "most of those patients at day 42 were as well or better than they were at day 15 . . . clearly, we have an overperforming placebo that throws off the graph." Defendant Greene further repeated that "what's really interesting about SHORELINE, and it's unique in the study of depression, is it's almost a reverse placebo effect."

159. Defendant Greene further overstated the Company's prospects for securing FDA approval, representing that the Company "sat down with the agency . . . after the MOUNTAIN study, which just barely missed [statistical significance] and all appreciated that we have a drug, zuranolone, that works." Defendant Greene added:

> So we sat down with the agency, we said, what's the right path to approval? We designed 2 studies for MDD: WATERFALL, which we read out positively; CORAL, which is coming up; and then another PPD study, SKYLARK. Any one of which, if positive, provided the efficacy data set to file on.

160. Defendant Greene claimed that "[w]e have the efficacy data we need for filing" and that Sage "confirmed" with the FDA "that statistical significance at day 15 is not necessarily a requirement for [the NDA's] filing." Defendant Greene continued, stating:

> So what we believe we have today is we have the efficacy data for a fileable package now that we have that next complete positive Phase III with WATERFALL. So we have the efficacy package. We've said -- we said at the beginning of the year, and we sort of have tried to repeat this, we chose to rerun the pharmacology studies at 50 milligrams. We had the 30-milligram complete, but we're rerunning them at 50. Those studies will be done kind of at the end of the year."
>
> Why? We didn't want to leave any room for interpretation about any boxes that didn't get checked as we filed for the NDA. This is a large indication, millions of patients. So we want to make sure that we provide the highest quality data package. We expect no surprises with the repeat pharmacology studies. And then because it's in zuranolone's best interest because of the clean safety profile, our intention is to take a blinded look at all safety on ongoing clinical studies as part of the package.

> Now we expect CORAL to be complete as we've guided. So with a complete CORAL, both efficacy and safety, that will get integrated into the package. But we've said historically, and we confirmed this with the agency, that unless we see some strange pattern, it doesn't work on day 3, 8, 12 or 15, that statistical significance at day 15 is not necessarily a requirement for filing. We have the efficacy data we need for filing. This is yet another study.

161. The host then questioned Defendant Greene with respect to the Company's communications with the FDA and whether Sage was "completely on board with the regulatory requirements," asking if it was "fair" to assume that "the last discussion [with the FDA] was the one that resulted in not requiring REDWOOD and RAINFOREST[.]" In response, Defendant Greene stated:

> [G]iven the breakthrough status that we have with zuranolone and given the way breakthrough works, there's ongoing discussions with the agency. Some of those discussions are more strategic, which leads to decisions to not run certain trials, like you mentioned.
>
> Some of the more tactical, in terms of dates and time and sort of administratively, do we do a rolling submission? Do we do a full submission? The kind of formal meeting where we do the official Type B NDA meeting, that's coming up in kind of weeks, not months. And once we have that formal meeting with sort of everybody present that locks in the data sets, all the administrative steps, as we've said before, we'll come out in a Reg FD format with Biogen and clarify what we believe we and the agency have agreed for the path forward. I do expect it to be as we've already articulated.

162. The statements identified above, issued by the Individual Defendants on August 11, 2021, were materially false and misleading because they continued to reference communications with the FDA that purportedly indicated that the Company was likely to secure approval. For instance, the Individual Defendants overstated the Company's prospects for FDA approval by representing, for example, that Sage "sat down with the agency . . . after the MOUNTAIN study, which just barely missed stat sig [statistical significance] and all appreciated that we have a drug, zuranolone, that works." Further, the Individual Defendants continued to claim that the Company already possessed sufficient data, without further positive results from trials, to secure FDA

approval.

163. On September 10, 2021, Defendant Greene attended the Morgan Stanley Global Healthcare Conference. At the conference, Defendant Greene reiterated that zuranolone "works rapidly" and claimed that "we see durable responses based upon the WATERFALL study and the SHORELINE study," adding that "nobody's imagined a world where you literally could treat someone with 2 weeks of evening therapy and get them better, faster and keep them better." With respect to the Company's non-public interactions with the FDA, Defendant Greene stated that "[w]hat the team did with the agencies [is] designed 3 different Phase IIIs, any one of which [if] hit based upon the rest of the data led to a fileable package, 2 in MDD and 1 in PPD," adding that Sage "talked to the agency about 4 different times" in developing these three approval paths, "any one of which [if] hit gave us a viable package."

164. During an analyst conference call on October 4, 2021, Defendant Greene responded to a question regarding "how sustained both the response and remission rates were at day 42" versus Day 15 and the "placebo rates of both of these measures" by representing that "consistency across all studies" and the "response/remission when coupled with all the other data" "gives us tremendous confidence in how zuranolone is performing." Defendant Kanes touted "both response and remission for longer duration," claiming that "[o]nce patients get better, they remain well."

165. On October 19, 2021, Sage issued a press release filed on a current report on Form 8-K with the SEC, announcing plans to file the NDA for zuranolone (the "October 19, 2021 Press Release"). The October 19, 2021 Press Release stated that "[f]ollowing the pre-NDA meeting, the companies confirmed the current efficacy and safety databases are expected to be adequate for filing with confirmed pathways for MDD and PPD." The October 19, 2021 Press Release quoted Defendant Greene as stating that "[i]n the pre-NDA meeting, the FDA's response on the regulatory

pathway for zuranolone continued to be consistent with previous discussions."

166. On November 2, 2021, Sage issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's third quarter 2021 financial results (the "3Q21 Press Release"). The same day, Sage filed a quarterly report on Form 10-Q with the SEC for its third quarter of 2021 (the "3Q21 10-Q") and held a related earnings call (the "3Q21 Earnings Call").

167. The 3Q21 10-Q continued to reference Auvelity (AXS-05), while failing to disclose the risk posed by the competitor to the Company's ability to secure FDA approval and its commercial prospects, stating that "[i]n April 2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which received Breakthrough Therapy designation for MDD in March 2019."

168. The 3Q21 Press Release quoted Defendant Greene, who referenced "a successful pre-NDA meeting with the FDA for zuranolone. . . . We're excited to have reached alignment with the Agency and to have what we believe is a clear, efficient path forward for zuranolone." The 3Q21 Press Release further represented that communications with the FDA "reinforced Sage's belief" that its clinical data "will be sufficient for Sage to file in MDD":

> The meeting reinforced Sage's belief that data from the MDD-201, ROBIN, and WATERFALL Studies and the Shionogi Phase 2 study along with supportive data from the MOUNTAIN Study will be sufficient for Sage to file in MDD. The planned initial NDA will focus on MDD and will also include data from the ongoing pharmacology and clinical studies (CORAL and SHORELINE Studies).

169. In the 3Q21 Press Release, the Company further announced that the primary endpoint for the CORAL Study (HAMD-17 change from baseline) will be measured at Day 3" (instead of Day 15), adding that CORAL was "an adjudicative use study in MDD designed to demonstrate the benefit of zuranolone when co-initiated with a new antidepressant therapy."

170. During the 3Q21 Earnings Call, Defendant Greene stated the following with respect to the Company's pre-NDA meeting with the FDA:

> This year and quarter have been marked by significant progress for Sage. We recently announced that following a pre-NDA meeting with the FDA, we and Biogen plan to submit an NDA for zuranolone in MDD in the second half of 2022, with an additional associated submission in PPD in the first half of 2023. We're pleased that we've reached alignment with the agency and believe we have a clear path for this submission. This brings us one step closer toward our goal of helping patients suffering from MDD and PPD.

171. Defendant Greene further stated that Sage "met with the agency in early 2020 and designed 3 distinct Phase III studies, 2 in MDD and 1 in PPD. . . . The plan set in motion was for a positive study from any 1 of the 3 paths to support an NDA filing and subsequent approval since it will provide the third positive pivotal study." Defendant Greene continued, stating:

> Based on the positive results from the WATERFALL study, we believe that we have the necessary data to submit an NDA for zuranolone. And we're delighted that our recent pre-NDA meeting with the FDA reaffirmed that belief. And now, in fact, we have 4 positive studies: MDD-201B, ROBIN, WATERFALL and the Shionogi Phase II study. The data we have generated in clinical development to date support our belief in the overall benefit risk of zuranolone.

172. Defendant Greene further repeated that the Company did "not believe CORAL efficacy data will be required for the MDD filing pathway" and that the data would merely "contribute to [the] overall safety database regardless of the outcome of the primary endpoint." Defendant Greene touted the Company's prospects for securing FDA approval because "the totality of data" purportedly demonstrated that "zuranolone has consistently demonstrated rapid and sustained reductions in depressive symptoms and a well-tolerated safety profile without the adverse events that are often associated with discontinuation of standard of care [antidepressant treatments]. Defendant Greene again referenced the Company's purportedly positive interactions with the FDA, stating that "[w]e've had a highly productive and transparent relationship with the agency and look forward to continuing to engage with them as we begin the rolling submission for

zuranolone planned to commence in early 2022."

173. Also during the 3Q21 Earnings Call, Defendant Doherty explained that the change in CORAL's primary endpoint was "in line with the goal of the study to demonstrate the rapid onset of zuranolone," adding that "including a trial with a day 3 primary endpoint may be a useful complement to the broad clinical package for zuranolone."

174. Defendant Doherty then referenced the KINETIC study, stating that the "statistically significant correlation between TETRA [sic] scores and activities of daily living observed at every time point" is "an important finding that demonstrates the reduction in tremor seen with SAGE-324 in the study translated to meaningful effects for patients."

175. In response to a question regarding whether "the CORAL primary endpoint change" was "FDA-driven or Sage-driven," Defendant Greene indicated that the change resulted from FDA "feedback," explaining that "we sought overall feedback on the CORAL study, statistical analysis plan from the agency. And after that feedback, we selected . . . the day 3 endpoint as the key primary endpoint really to get back to the original idea of the CORAL study, which is to demonstrate . . . the rapid relief of depressive symptoms early in clinical trials." Defendant Greene then reiterated that the Company "already had the efficacy data in hand for filing," which "allowed us now to move the primary endpoint to CORAL II to day 3." Defendant Greene then indicated that the Company's communications with the FDA during the pre-NDA meeting signaled that Sage would have to shift focus to the speed of zuranolone's effectiveness, stating that "we believe after the pre-NDA meeting that we have, the package to file, so it was important for us to have day 3 reflect that rapid onset."

176. When probed further regarding whether the Company's conversations with the FDA indicated that "statistical significance at [] later time points isn't really a hurdle," Defendant

Greene stated that "clinical significance at the later third point is not required. . . . What the agency and what physicians look for is consistent and durable impact without a rapid return to baseline," adding that out of 4,000 patient subjects, "we've seen rapid benefit at day 3 with continued benefit out to day 42, and again, on SHORELINE, even longer term feedback."

177. An analyst then expressed confusion as to why the Company was not using existing Day 3 efficacy and response data for the NDA filing if "we knew all along that day 3 will show statistical separation," asking "[w]hy do you guys keep saying that we shouldn't—we don't need it," and "why change it so close to [the] rolling NDA [submission]?" In response, Defendant Greene stated:

> I'll remind you that in 2020, our team sat down with the agency following a number of Phase III studies, one, recognizing that MDD was the major unmet need and, in fact, a growing unmet need. So we and the agency and others appreciated that we needed something in addition to the currently approved antidepressants where we haven't seen a change in benefit/risk in a long time, and designed the LANDSCAPE and NEXT programs, 2 MDD studies and 1 PPD study. And we highlighted, and this is going back to consistent with our guidance in January that we needed 1 more positive study to have the package to file. We've got that and more we got the Japanese positive study as well.
>
> So we sat down with the agency in our pre-NDA meeting and confirmed that, that data package was sufficient for filing and that another Phase III was not required. But there was a dilemma in front of us, as we highlighted. We had 2 ongoing Phase III studies. So we had what I thought was a very good open strategic discussion with the agency, which said like, 'CORAL's coming up, let's file for MDD.' We're going to include CORAL in the filing, but the efficacy data is not necessarily required to be positive to file.
>
> Now the change to day 3 will benefit us if, in fact, day 3 is positive, and we see benefit over the treatment course. Those data will be incredibly important to guide our medical affairs force, our sales force in educating physicians about the appropriate use of zuranolone, including the totality of data.

178. The statements identified above, issued by the Individual Defendants between September 10, 2021 and November 2, 2021, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. In addition,

the Individual Defendants changed the CORAL study's primary endpoint from Day 15 to Day 3. Day 15 was the MOUNTAIN study's unsatisfied primary endpoint from years earlier. By contrast, the Individual Defendants knew that zuranolone could meet the new primary endpoint of Day 3. Moreover, the Individual Defendants referenced non-public and unverifiable communications with the FDA to justify this change.

179. On November 15, 2021, Defendant Greene participated at the Stifel Healthcare Conference on behalf of Sage. In his introductory remarks, Defendant Greene represented that "we feel like we've gotten real good strategic alignment with the [FDA] and real good clarity on moving forward."

180. In response to a question regarding "CORAL and the recent change that you made at day 3," Defendant Greene merely restated that the Company had "3 different Phase III studies, 2 in MDD, 1 in PPD that we believed [if] any one of which is positive gave us the filing package."

181. Later during the conference, Defendant Greene continued to minimize the correlation between zuranolone and placebo and emphasized that "there's evidence that these patients get better and stay better" and "that's what" the FDA and others are "looking for":

> What we're looking at and what medical folks believe and the agency believes is that if someone can get better and stay better, that's what we're looking for. Having a robust placebo effect, which we're seeing across all depression trials is a part of running depression trials. It's inappropriate to use the words, the drug loses effect. In fact, at day 42, we saw 86% of the day 15 effects. The drug is not losing effect, having low dose placebo narrows that. Now what we don't want to see and we're not seeing this is that someone gets better, they stay better at 15. And then as soon as they're off the drug, they quickly rebound back to baseline.

182. With respect to SAGE-718, Defendant Greene stated that "if you think about what we saw with Huntington's Disease, not only did they [patients] not get worse, they got better in 2 weeks, which is quite remarkable. We saw that repeating in Parkinson's. . . . SAGE-718 is fundamentally overlooked in terms of the massive value it can create." Defendant Greene

expressed similar confidence regarding SAGE-324:

> [R]ight now, we're initiating a Phase II study testing various doses and frequency so that we believe that in addition to that 35% to 45% decrease in essential tremor, which also led to an improvement of activity with daily living that we have a drug that people can take chronic. So that's what we're studying now. We're very confident based upon our read of the data that we'll get there. They'll have both efficacy and then the drug that someone can take chronically because it is a condition that requires chronic administration.

183. The statements identified above, issued by the Individual Defendants on November 15, 2021, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. Specifically, the Individual Defendants overstated the efficacy and durability of the Company's three main drug candidates. Further, in response to a question regarding the change in CORAL's primary endpoint, Defendant Greene claimed that the Company had "3 different Phase III studies, 2 in MDD, 1 in PPD that we believed [if] any one of which is positive gave us the filing package," indicating that the change merely supported other data that was already sufficient for FDA approval.

184. On December 1, 2021, Sage issued a press release filed on a current report on Form 8-K with the SEC, which discussed results from the Company's SHORELINE study for zuranolone, reporting on mild side effects including "somnolence, dizziness, sedation, and tremor," and quoting Defendant Greene as stating the following regarding the purported efficacy of zuranolone demonstrated by the study:

> We believe zuranolone has the potential to offer an innovative treatment approach that may enable patients with MDD to experience reductions in depressive symptoms quickly, achieve related improvements in functioning and well-being, and maintain long treatment free intervals without the types of burdensome side effects that are often associated with discontinuation of standard of care antidepressants.

185. The same day, Defendant Greene participated at the Piper Sandler Healthcare Conference on behalf of Sage. At the Conference, Defendant Greene discussed results from the

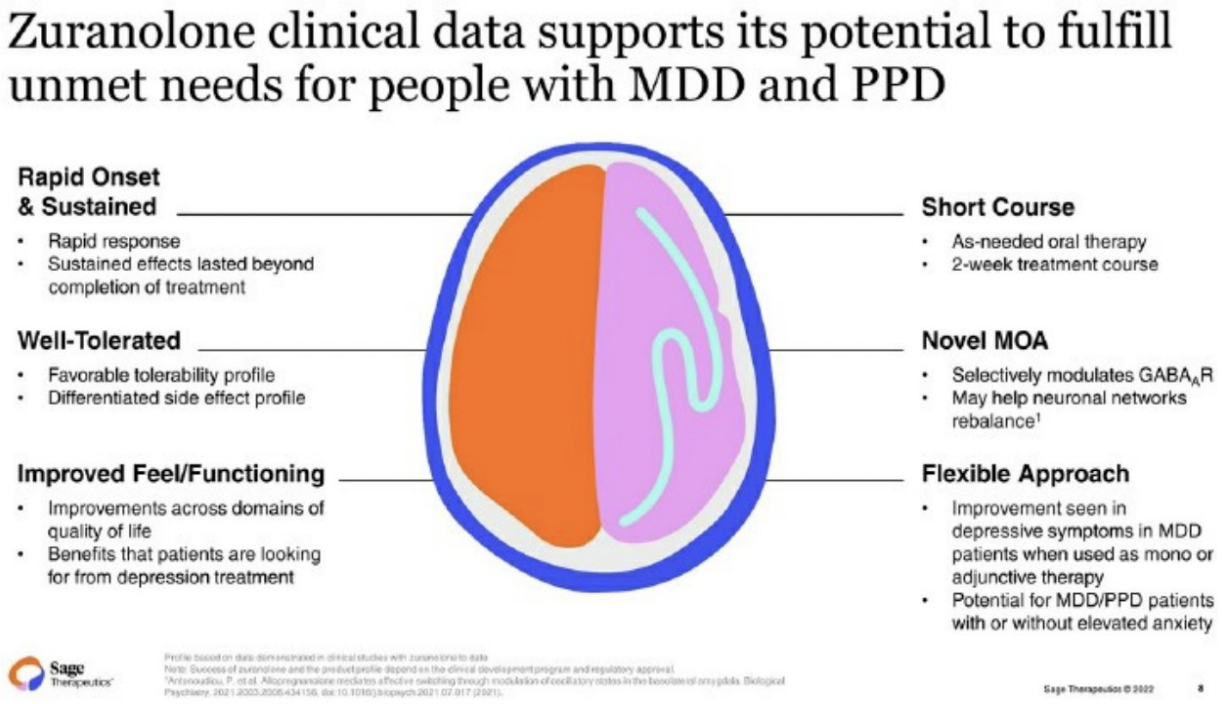
SHORELINE study and stated that the safety profile of the 50 mg dosage of zuranolone was "very much like" that of the 30 mg dose. Defendant Greene compared zuranolone to a "Z-Pak if you've got a lower respiratory tract infection," adding: "It might work in 14 days. You might need to recourse." Defendant Greene further repeated previous statements that the FDA had indicated in its communications with the Company that there were three pathways to securing approval for zuranolone: ""two in MDD and one [i]n PPD." Defendant Greene added that, "[w]ith the positive WATERFALL [trial results], we confirmed with the FDA in our pre-NDA meeting that WATERFALL plus the rest of the data was sufficient for filing [the NDA], so we're moving forward."

186. In response to a question regarding what the "FDA [will] focus on" for approval, Defendant Greene stated that "we know from discussions with the agency and as evidenced actually by the ZULRESSO AdComm, that what they're looking for is a rapid response and a sustained response without rebound. So we do have that in all of our trials out at day 42 . . . both the physician assessment but, even more importantly, the patient-blinded assessment suggest that those on drug stay better and are statistically significantly better at day 42."

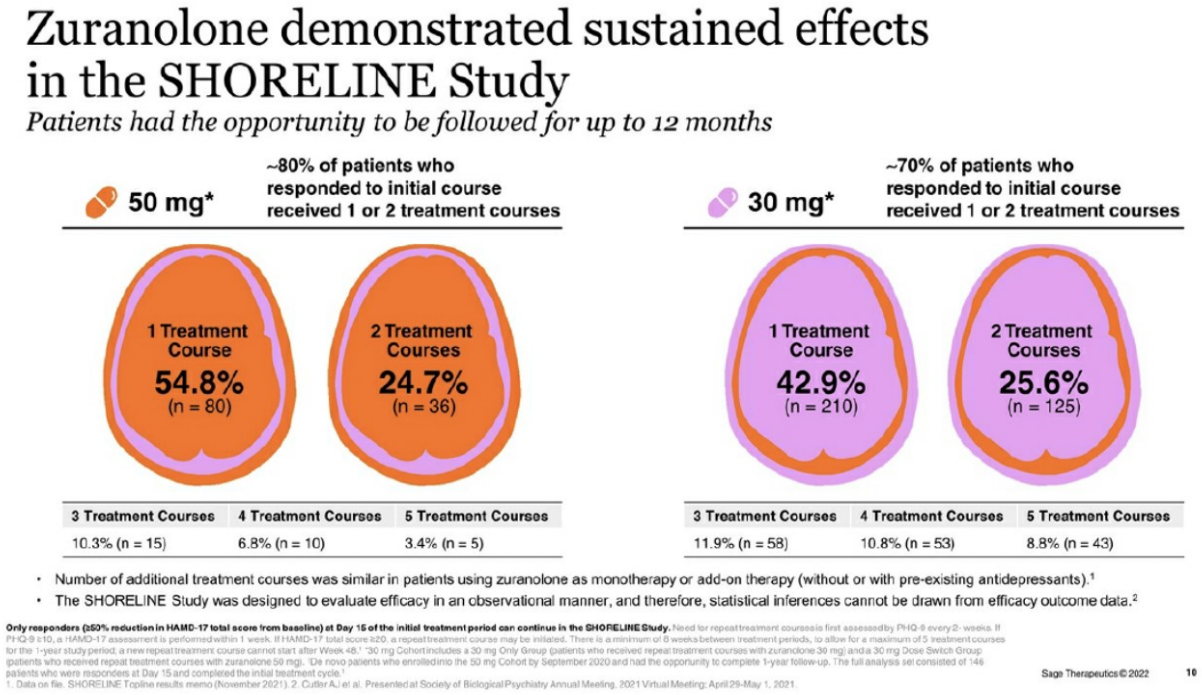
187. The statements identified above, issued by the Individual Defendants on December 1, 2021, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. Specifically, the Individual Defendants overstated the efficacy and safety of zuranolone, reporting only mild side effects like "somnolence, dizziness, sedation, and tremor." In reality, the use of zuranolone, like many antidepressants, was associated with some degree of suicidal ideation and self-harming behaviors. Further, it was misleading to suggest that patients using zuranolone "are statistically significantly better at day 42," as zuranolone never exhibited statistical significance at Day 42 in the treatment of MDD.

Instead, the drug demonstrated statistical significance only at earlier endpoints, such as Day 3, in WATERFALL, as reported by the Company on December 8, 2021.

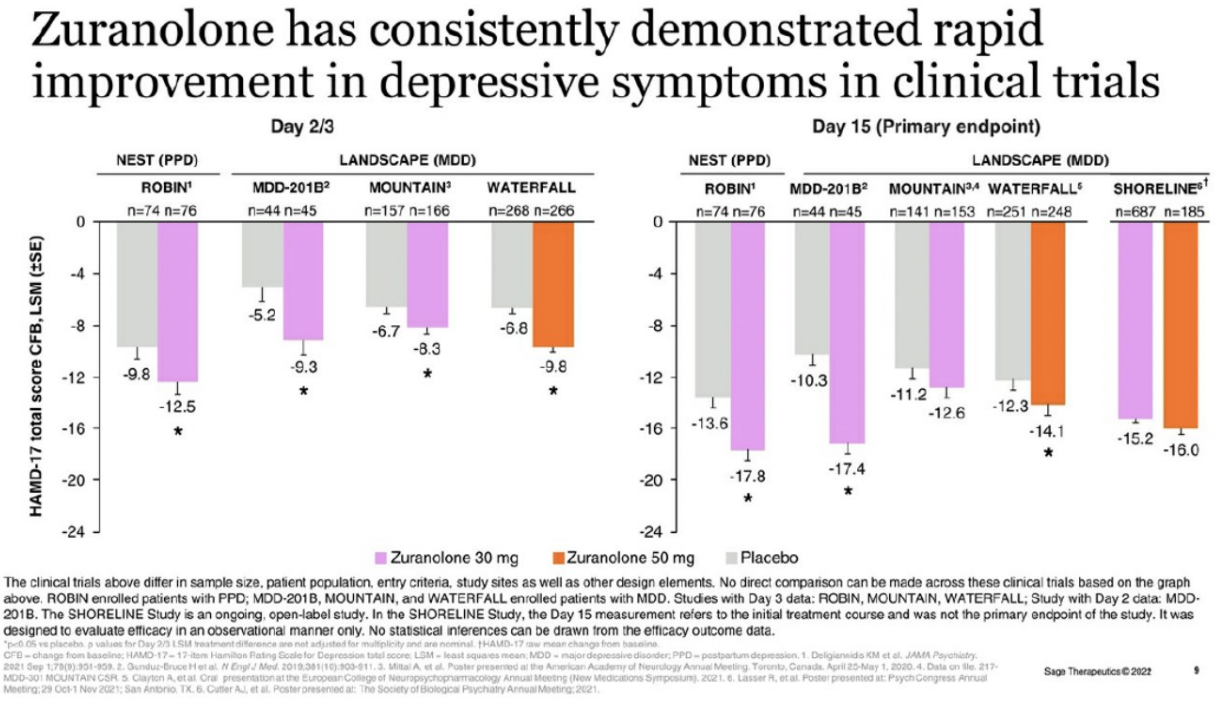
188. On January 10, 2022, the Company attached a presentation for the 40th Annual J.P. Morgan Healthcare Conference to a current report on. Form 8-K. With respect to zuranolone, the presentation included a slide which indicated that zuranolone's "sustained effects lasted beyond completion of treatment":



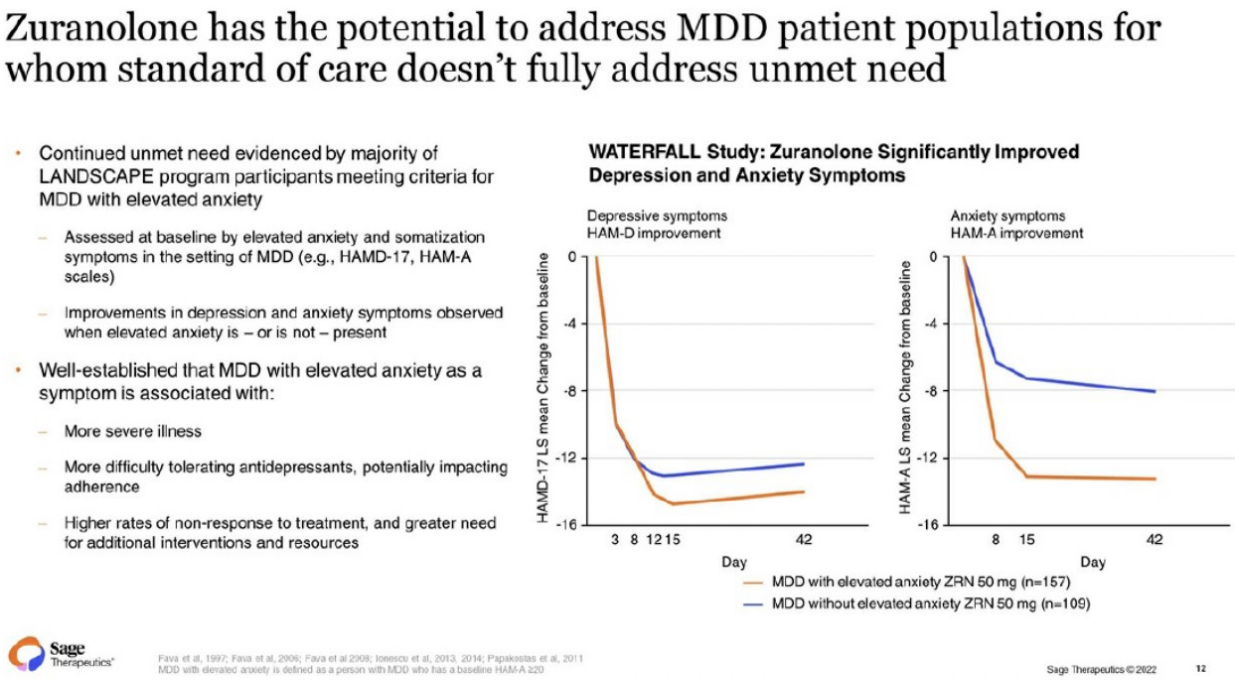
189. The presentation also included the following slide, discussing the purported "sustained effects" demonstrated by zuranolone:



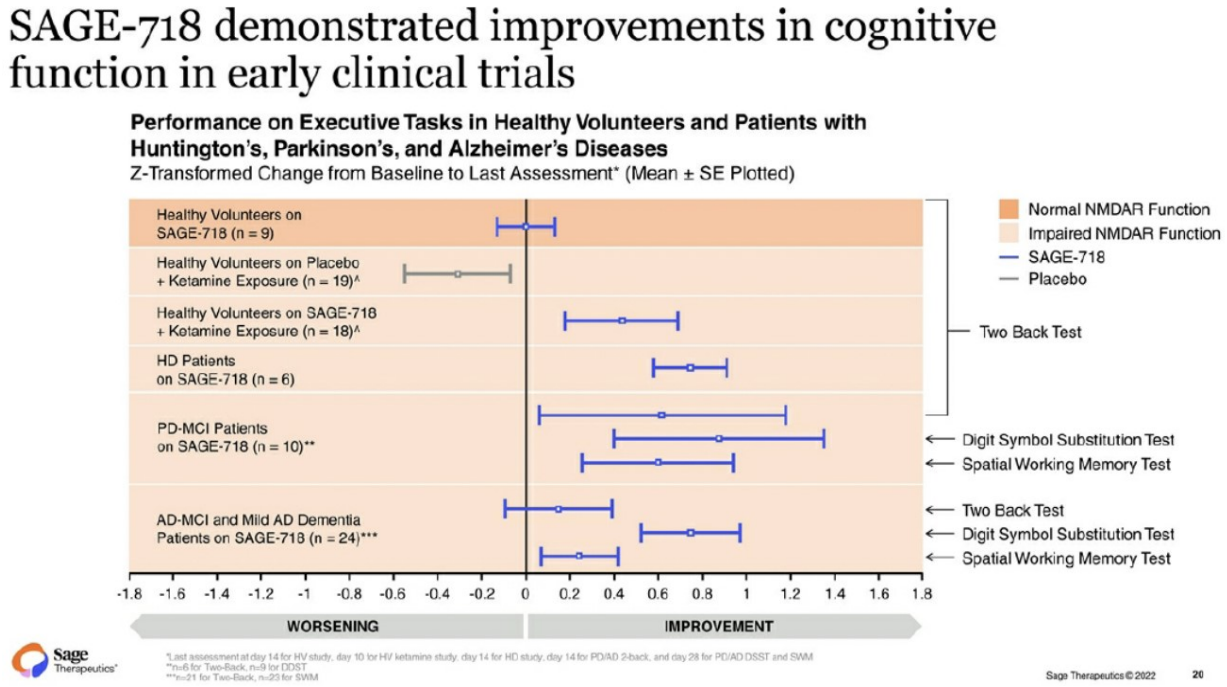
190. The presentation reported that 30 mg and 50 mg doses of zuranolone outperformed the placebo:



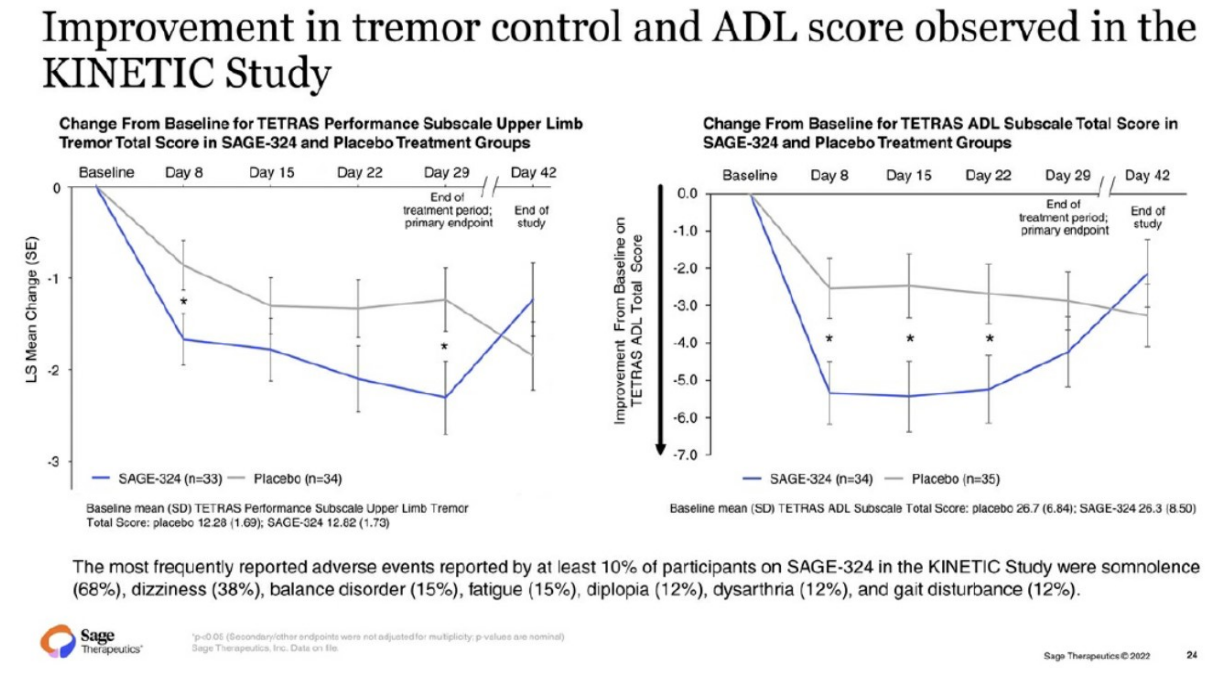
191. The presentation further included the following slide, highlighting the purported efficacy of zuranolone in treating depression and anxiety:



192. The presentation highlighted the size of the market for zuranolone, estimating the t19.4 million adults with MDD could be potential candidates for the drug. Additionally, the presentation touted the efficacy and commercial prospects for SAGE-718 and SAGE-324. For example, the presentation estimated the aggregate market size of patients with Huntington's, Parkinson's, and Alzheimer's Diseases at over 140 million, and included the following slide highlighting SAGE-718's "demonstrated improvements in cognitive function in early clinical trials":



193. The presentation estimated that 136.4 million people suffer from essential tremor or Parkinson's Disease, highlighting "[i]mprovement in tremor control and ADL score observed in the KINETIC Study" of SAGE-324:



194. The presentation included statements that were materially false and misleading and omitted to state material adverse facts necessary to make the statements not misleading because they overstated the efficacy of zuranolone, SAGE-718, and SAGE-324 on the basis of data from studies that were not designed to evaluate long-term efficacy. Indeed, the SHORELINE study referenced in the presentation was designed merely to "evaluate efficacy in an observational manner," precluding the Company from drawing statistical significance from the results.

195. The conference took place the following day. During the conference, Defendants Greene, Iguchi, and Doherty referenced the presentation and repeated the false and misleading statements contained therein. In his opening remarks, Defendant Greene emphasized "the rapid reduction in depressive symptoms we've seen with zuranolone in clinical trials in MDD and PPD to date," highlighting "significant reductions in depressive symptoms" after only "1 or 2 evening oral doses, and of course, robust reductions at day 15." Defendant Greene added that the "integrated analysis from [Sage's] completed pivotal placebo-controlled study in MDD and PPD" demonstrated that "patients who received zuranolone demonstrated statistically significant improvements from baseline across assessments of well-being and functioning at both day 15"—"a day off drug"—and Day 42, as "compared to patients who received placebo."

196. Comparing zuranolone to FDA-approved treatments for MDD, Defendant Greene stated that zuranolone's "potential benefit risk profile . . . may be distinct from current antidepressants. . . . The integrated response and discontinuation data generated with zuranolone studies to date shows higher response rates and much lower discontinuation rates."

197. With respect to the Company's two other primary drug candidates, Defendant Green stated that "SAGE-718 has demonstrated improvement on important test of executive function across multiple studies," and SAGE324 exhibited "statistically significant reductions in

tremor as measured by TETRAS upper limb tremor score . . . through day 29," and "statistically significant improvements in activities of daily living as measured by the TETRAS-ADL scale."

198. During the conference, the host questioned "the rationale of moving the primary endpoint [for CORAL] from day 15 to day 3," and the importance of "later time points, day 15 as well as day 42, both to physicians and to regulators when it comes to assessing the profile of zuranolone." In response, Defendant Greene stated that, in 2021, we had a good meeting with the FDA about the totality of zuranolone data," and, "in conjunction with the agency, designed 3 Phase IIIs, 2 an MDD called LANDSCAPE, 1 in PPD called NEST, that the agency guide us if any 1 of which of these Phase IIIs was positive, we had a fileable package." Defendant Greene added that the Company "had a meeting with the FDA" in late 2021, where "we confirmed that a positive WATERFALL presented a fileable package" and "confirmed that the agency would like us to start the rolling [NDA] submission." Defendant Greene elaborated, explaining that establishing a primary endpoint at Day 3 enabled CORAL to further confirm zuranolone's fast efficacy. Defendant Greene cited the Company's experience with Zulresso, stating that "we know this from the ZULRESSO experience we had, where what regulators are looking for is consistency or durability of effect irrespective of what placebo does"—that is, lack of "a rebound of effect."

199. The statements identified above, issued by the Individual Defendants at the 40th Annual J.P. Morgan Healthcare Conference were materially false and misleading for many of the reasons that the Individual Defendant's previous statements were misleading. Specifically, the Individual Defendants overstated the efficacy and durability of its three primary drug candidates. Further, Defendant Greene's reference to Zulresso served to encourage public confidence in the Company's ability to secure FDA approval for zuranolone. However, this was misleading because Zulresso is a fundamentally different drug. It is used for the treatment of PPD, and at the time, it

was the only treatment available for the treatment of PPD. Further, Zulresso was approved for a narrow and well-defined patient population, who typically do not need treatment for as long as patients suffering from MDD.

200. On February 16, 2022, Sage issued a press release and hosted a conference call to discuss the topline results of the CORAL study on zuranolone for use in the treatment of MDD (the "February 16, 2022 Press Release" and the "February 16, 2022 Analyst Call"). The February 16, 2022 Press Release reported that the drug met its primary and secondary endpoints, stating that "at the Day 3 primary endpoint, zuranolone 50 mg co-initiated with a standard of care antidepressant showed a statistically significant reduction in depressive symptoms" and, for the key secondary endpoint, "zuranolone co-initiated with an antidepressant was statistically significant in reducing depressive symptoms compared to an antidepressant co-initiated with placebo over the 2-week treatment period."

201. The February 16, 2022 Press Release additionally stated that "[o]ther secondary endpoints demonstrated a statistically significant reduction in HAMD-17 score in the zuranolone co-initiated with ADT [antidepressant] arm compared to the ADT arm at Days 8 and 12, while Day 15 demonstrated numerical superiority and Day 42 showed equivalence."

202. The February 16, 2022 Press Release quoted Defendant Greene as stating the following:

> We believe the CORAL Study is clinically meaningful and with the addition of this data the LANDSCAPE program now demonstrates zuranolone has three potential real world uses for the treatment of MDD. The LANDSCAPE data support zuranolone as a monotherapy, and since many people in the previously completed studies were already on maintenance ADTs, we believe our data also support zuranolone as additive therapy. The CORAL Study further supports the use of zuranolone to accelerate the benefit of conventional ADTs in treating MDD with a well-tolerated safety profile," said Barry Greene, Chief Executive Officer at Sage. "Including the CORAL Study, zuranolone now has six positive clinical studies, and we remain on track to start the rolling submission for a New Drug Application in

MDD early this year with completion targeted for the second half of 2022.

203. During the February 16, 2022 Analyst Call, Defendant Greene restated CORAL's topline results, including that "zuranolone co-initiated with standard-of-care antidepressants or ADTs met the primary endpoint," "demonstrating a statistically significant reduction in HAMD-17 scores at day 3 . . . [as] compared to standard-of-care antidepression co-initiated with placebo." Defendant Greene represented that the key secondary endpoint was met, with "a statistically significant improvement in depressive symptoms . . . over the 2-week treatment period," meaning that "zuranolone showed continuous benefit over the treatment period." Defendant Greene added that "no new safety signals [were] attributable to zuranolone." Defendant Greene again referenced the Company's communications with the FDA, stating:

> [F]ollowing our pre-NDA meeting with FDA in late 2021, we confirmed our belief that we had the data needed to submit an NDA for MDD for zuranolone. Given our confidence in the data package to support the filing, we announced that the primary endpoint in the CORAL Study will be measured at day 3 because we believe that demonstrating rapid reduction in depressive symptoms at day 3 is an important differentiator and informs potential real-world use of zuranolone.

204. With respect to the side effects of zuranolone, Defendant Doherty stated that "adverse events reported in the study were mild or moderate in severity, consistent with previous data in the LANDSCAPE program," adding that, "importantly, there were no signals for increased suicidality or withdrawal symptoms in the study." Defendant Doherty also touted zuranolone's "rapid and sustained efficacy."

205. Defendant Greene claimed during the February 16, 2022 Analyst Call that zuranolone's "rapidity of effect," "particularly" for "MDD [patients] with elevated anxiety" is "a real differentiator" compared to other MDD treatments. Defendant Greene expanded on that point, stating that "it takes 6 to 8 weeks for people to see benefit" from existing MDD drugs and patients often "drop off" of those drugs before then "because of side effects."

206. Also during the February 16, 2022 Analyst Call, Defendant Benecchi touted zuranolone's "sustained or durable effect over time" and "safety profile." With respect to the size of the patient population suffering from "MDD with elevated anxiety," Defendant Benecchi stated that it ranges from "54% to 66% of [MDD] patients cited in [the] studies" to "in excess of 70%" of MDD patients "in the real world, as you talk to practicing clinicians." Defendant Benecchi concluded that zuranolone "for the first time, gives [clinicians] the opportunity to treat a patient with MDD with elevated anxiety in a way that provides that rapid and durable effect over time through a short course without the stigmatizing side effects of sexual dysfunction and weight gain that they see with other ADTs."

207. Later during the February 16, 2022 Analyst Call, Defendant Greene stated that "after our pre-NDA meeting" in 2021, the Company determined that it "had the fileable package to move forward with" and then "confirm[ed] that with the agency," deciding "with Biogen, [and] the agency to have CORAL . . . show the rapidity of effect when co-initiated with an antidepressant." Defendant Greene further stated:

> [W]hen we met with the agency, they were very helpful in guiding us, suggesting that, look, we've got 2 outstanding Phase IIIs, one in MDD, one in PPD. Let's complete the MDD study, include that in the filing and file for MDD. And then once you complete the PPD study, file for PPD. And the window is such that we might be able to kind of launch both indications at the same time.

208. In response to a question regarding the efficacy retention for CORAL and how it impacts regulatory approval, Defendant Doherty stated that Sage "didn't calculate it in this study," but that the "response retention would actually be over 100%" in terms of absolute scores because patients "continued to improve over the duration of the study." Defendant Doherty again attempted to minimize the importance of the Day 42 equivalence with placebo.

209. The statements identified above, issued by the Individual Defendants on February 16, 2022, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. Specifically, the Individual Defendants continued to allude to non-public interactions with the FDA to suggest that the agency approved of the methodologies employed in the Company's studies and to instill public confidence regarding the Company's prospects for securing FDA approval. The Individual Defendants further continued to overstate the efficacy of zuranolone and downplay the significance of the placebo effect in the Company's studies.

210. Despite the Individual Defendants' attempts to assuage public concern related to the news that "Day 42 showed equivalence" in the CORAL study, the market responded negatively to the disclosure. The price of Sage stock declined 22.8% on this news, from a close of $43.50 per share on February 15, 2022 to a close of $33.58 per share on February 17, 2022.

211. On February 24, 2022, the Company issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's fourth quarter and full year 2021 financial results (the "FY21 Press Release"). The same day, Sage hosted a related earnings call (the "FY21 Earnings Call") and filed its 2021 annual report on Form 10-K with the SEC (the "2021 10-K"), which was signed by Defendants Greene, Iguchi, Jonas, Cola, Paul, Starr, Frates, Germano, Barrett, and Golumbeski.

212. The 2021 10-K continued to reference Auvelity, while failing to disclose the risk posed by the competitor to the Company's ability to secure FDA approval and its commercial prospects, stating:

> In April 2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which has previously received Breakthrough Therapy designation for MDD, but the expected Prescription Drug User Fee Act, as amended, or PDUFA,

target action date of August 2021 has been delayed.

213. During the FY21 Earnings Call, Defendant Greene opened by stating that "up to 2/3 of people with MDD experience elevated anxiety symptoms." Defendant Doherty agreed that MDD patients with elevated anxiety constituted "up to 66% of all MDD patients" who are "less responsive" to other treatments. Defendant Doherty then claimed that "WATERFALL and SHORELINE studies identified MDD with elevated anxiety at baseline as a subgroup that is particularly responsive to zuranolone." Reflecting Sage's new focus on MDD with elevated anxiety, Defendant Greene stated that the Company "did a retrospective analysis across our data and discovered that zuranolone was particularly useful in . . . MDD with elevated anxiety," prompting Sage to "prospectively" design "that subpopulation into the CORAL study." Defendant Greene repeated that that subpopulation is "about 2/3 of those annually diagnosed with MDD" and represented that "we have a very rich package for MDD with a pre-defined subpopulation [in] MDD with elevated anxiety" and "we're quite enthusiastic about the regulatory path forward."

214. Defendant Greene further stated that Sage "reiterated the consistency of discussions we've had with the [FDA] that WATERFALL constitute a filing package." With respect to those discussions, Defendant Greene stated that, at the time, "there were 2 outstanding studies, 1 in [MDD] CORAL and one in PPD SKYLARK, and [the FDA] suggested and we agreed that we first filed an MDD, including the CORAL study and then with PPD, including the SKYLARK study."

215. The statements identified above, issued by the Individual Defendants on February 24, 2022, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. Specifically, the Individual Defendants continued to allude to the Company's interactions with the FDA to instill public confidence in

Sage's prospects for securing FDA approval for its drug candidates. Further, the Individual Defendant continued to conceal the risks associated with Auvelity to zuranolone's commercial prospects and regulatory pathway.

216. On March 7, 2022, Defendant Greene participated at the Cowen 42nd Annual Healthcare Conference on behalf of Sage. During the conference, the following exchange occurred between the host and Defendant Greene:

> **Conference Host**
> The first issue is the zuranolone MDD filing. Now that you have CORAL successfully behind you, statistical significance, it doesn't look like there's anything there that is necessarily going to be problematic for the filing. But folks want to know what's left?
>
> **Defendant Greene**
> So we're in really good shape with the planned rolling submission of the NDA for zuranolone, which as you know, we're developing for the treatment of MDD and PPD. If I just take a step back and set some context, we started last year highlighting that we had 3 ongoing Phase 3 studies, 2 in MDD and 1 in PPD, any one of which if positive, constitute a filing, a positive filing. With positive [WATERFALL] last year, we met with the agency in the fall for a pre-NDA meeting, a formal pre-NDA meeting. We confirm that [WATERFALL], [i]n fact, was the last remaining piece to start an NDA and we're in good shape to do that. And as you mentioned, having a positive CORAL as part of that NDA is very, very helpful and will be instrumental as we commercialize.

217. Defendant Greene further referenced a previously undisclosed "Japanese study," conducted by Shionogi, that he characterized as "the only pure placebo-controlled study where zuranolone was studied [at dosage of] 20 and 30 milligrams and demonstrated clinically relevant and statistically significant improvement in depressive symptoms at day 3, 8 and 15." When asked whether "Shionogi is planning on presenting that [study] anywhere," Defendant Greene stated that he was unaware, explaining that "[i]t's really up to them to present as with many Japanese companies, they tend to be a little bit more conservative and really focus on kind of the regulatory focus."

218. Later during the conference, Defendant Greene stated the following with respect to the Company's interactions with the FDA:

> Well, we have the data to follow. When we met with the agency in the fall of last year, we confirm that the efficacy studies that we talked about, overall safety in over 3,500 patients was sufficient for filing. So we have the data we need to file right now. What's important is the FDA has communicated that real-world evidence increasingly plays a role as a component of regulatory decision-making. So we're confident that SHORELINE, which is the largest prospective natural study done to date in MDD really aligns with FDA's efforts to emphasize real world evidence, and it's potentially transformative in the treatment of depression. So we've got the data we need.

219. With respect to the durability of zuranolone in treating MDD, Defendant Greene stated that "a majority of patients take [the] drug for 2 weeks and are better for a long period of time," later quantifying that he meant "over a year":

> [W]hat I can say is that in the 50-milligram cohort, the majority of patients who responded to the initial zuranolone treatment received only 2 courses across the entirety of the year, 80% only needed 1 or 2 week courses. So that implies that those that responded did well for a long period of time.

220. The host sought clarity with respect to the foregoing representation, stating: "It sounds like you're saying that the average time point of redosing is further out. It's not close into that original, it's further out." In response, Defendant Greene stated that "[w]e're not ready to present that, but that's a good inference from the overall data set." Defendant Greene then suggested that the FDA might not hold an Advisory Committee meeting for zuranolone's NDA, stating that "[u]ltimately, it's an agency decision whether to have an AdComm or not. If they do decide to have it, we'll embrace it."

221. With respect to SAGE-342, Defendant Greene stated that the Company was "highly confident looking at the data that we'll have a dosing regimen that provides coverage for essential tremor without any tachyphylaxis with a profile that allows some to [sic] standard drug for long periods of time without discontinuation rates."

222. With respect to the Company's ongoing testing of SAGE-718, the host referenced Parkinson's and Alzheimer's Diseases, asking "how much buy-in do you have from FDA on what the approvable endpoint for PD and AD cognition is." In response, Defendant Greene stated that "we're very well aligned with the agency in terms of forging new pathways. . . . So we're in good shape and moving forward."

223. The statements identified above, issued by the Individual Defendants at the Cowen 42nd Annual Healthcare Conference, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. Specifically, the Individual Defendants overstated the efficacy and durability of zuranolone demonstrated by the Company's clinical trials. Further, the Individual Defendants overstated the efficacy of SAGE-324 and SAGE-718, representing that Sage was "highly confident" that SAGE-324 could treat "essential tremor without any tachyphylaxis" and that the Company was "well aligned with the [FDA] in terms of forging new pathways" for securing approval of SAGE-718.

224. On April 28, 2022, Sage filed a proxy statement on Form DEF 14A with the SEC (the "2022 Proxy"), soliciting shareholder approval for, *inter alia*, the re-election of Defendants Frates, Golumbeski, and Starr to serve for another three-year term on the Company's Board and the compensation of certain of the Company's executive officers, including Defendants Greene, Iguchi, Benecchi, Jonas, and Robichaud.

225. With respect to the WATERFALL study, "evaluating zuranolone 50 mg in adults with MDD," the 2022 Proxy reported that the study "met its primary endpoint."

226. With respect to the KINETIC study of SAGE-324, the 2022 Proxy reported that the study "had achieved its primary endpoint."

227. The 2022 Proxy highlighted "multiple development milestones in 2021

evaluating SAGE-718 for the treatment of cognitive impairment associated with Huntington's disease, Parkinson's disease and Alzheimer's disease, including receipt of Fast Track Designation for SAGE-718 in the treatment of Huntington's disease."

228. With respect to the Company's internal controls and legal and regulatory compliance the 2022 Proxy stated that "the Audit Committee operates under a written charter approved by the Board of Directors, which provides that its responsibilities include the oversight of the quality of our financial reports and other financial information and our compliance with legal and regulatory requirements" and "reviewing with management and our independent registered public accounting firm the adequacy of our internal controls over financial reporting."

229. With respect to the Company's risk assessment and risk management functions, the 2022 Proxy stated:

> Our Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board of Directors performs this oversight role by using several different levels of review. In connection with its reviews of our operations and corporate functions, our Board of Directors addresses the primary risks associated with those operations and corporate functions. In addition, our Board of Directors reviews the risks associated with our business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.
>
> Each of the committees of our Board of Directors also oversees the management of our risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Financial Officer provides reports to the Audit Committee and is responsible for identifying, evaluating and implementing financial risk management controls and methodologies to address any identified risks. In connection with its risk management role, our Audit Committee meets privately with representatives from our independent registered public accounting firm, and privately with our Chief Financial Officer. The Board of Directors evaluates from time to time the processes by which our exposure to risk is assessed and managed by management. In addition, the Audit Committee assesses our financial controls, legal and compliance risks, business and operational risks, and cybersecurity risks. As part of this oversight, the Audit Committee receives periodic reports from management on such risks at its regularly scheduled meetings, evaluates actions management has taken to limit, monitor or control such risk

exposures, and provides periodic updates to the full Board of Directors.

230. On May 2, 2022, the Company issued a press release, announcing the initiation of the rolling submission of the NDA for FDA approval of zuranolone for the treatment of MDD. Sage disclosed that it expected to complete the submission of the NDA for FDA approval of zuranolone for the treatment of MDD in the second half of 2022, followed by a filing for PPD in the first half of 2023.

231. On May 3, 2022, Sage issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's first quarter 2022 financial results (the "1Q22 Press Release"). The same day, Sage filed a quarterly report on Form 10-Q with the SEC for its first quarter of 2022 (the "1Q22 10-Q") and held a related earnings call (the "1Q22 Earnings Call").

232. The 1Q22 10-Q stated the following with respect to Auvelity:

> In April 2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which had previously received Breakthrough Therapy designation for MDD, but the expected Prescription Drug User Fee Act target action date of August 2021 has been delayed. In April 2022, Axsome announced that it had received and agreed to post-marketing requirements/commitments proposed by the FDA with respect to AXS-05 and in May 2022, Axsome announced that it anticipates potential FDA action on its NDA in the second quarter of 2022.

233. During the 1Q22 Earnings Call, Defendant Greene attempted to distinguish zuranolone from existing MDD treatments, stating that "zuranolone's mechanism of action is distinct from current antidepressants," emphasizing that "MDD studies to date . . . have included both patients with elevat[ed] anxiety as a symptom of their depression and those without symptoms of anxiety," meaning "zuranolone may be well suited to address a clear unmet need for people with MDD regardless of their baseline anxiety symptoms."

234. Defendant Doherty expressed similar confidence regarding the efficacy of zuranolone in treating patients with elevated anxiety, referencing "conversations with the FDA to

date" with respect to zuranolone's potential approval for use in the treatment of PPD and stating that "because PPD often presents very similar to MDD with elevated anxiety, we are encouraged by the positive results we've seen in patients with MDD presenting with elevated anxiety as a symptom of the depression in the LANDSCAPE program."

235. An analyst then asked a question regarding "potential dosing regimens" for SAGE-718, given "results in both Parkinson's and Alzheimer's suggesting a durable benefit beyond the dosing period." In response, Defendant Greene stated that SAGE-718 "will be chronically dosed," adding that "we don't see any kind of tolerability challenges or tachyphylaxis that would warrant any kind of periodic dose or dose disruption."

236. Defendant Greene then represented that, with respect to zuranolone, patients experienced fewer negative side effects from redosing, claiming that "We have not seen any additive safety with retreat. In fact, of the adverse event numerically, [it] actually goes down with each and every course."

237. Later during the 1Q22 Earnings Call, an analyst asked a question regarding "the timing of PPD and MDD approvals" and whether the FDA might approve zuranolone for PPD before MDD. In response, Defendant Greene stated that the Company was "very much aided by our strategic discussion with the agency in the fall of last year . . . we had alignment with the agency that we needed one more positive study . . . the strategic discussion said, let's file MDD first . . . and then file PPD."

238. The statements identified above, issued by the Individual Defendants on November 15, 2021, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. Specifically, the Individual Defendants continued to conceal the risks posed by FDA approval of Auvelity to the Company's regulatory

pathway and commercial prospects. Further, the Individual Defendants continued to overstate the safety and efficacy of zuranolone and to overstate the long-term efficacy of SAGE-718.

239. On May 11, 2022, Defendants Benecchi and Robichaud participated at the Bank of America Securities 2022 Healthcare Conference on behalf of Sage.

240. Defendant Benecchi began by conveying the advantages of a rolling submission, stating that it "allows us to get our material in front of the FDA as soon as possible." When questioned "about the potential for having an AdComm," Defendant Robichaud identified "durability" and "utility" as considerations that "are probably . . . very important" to the FDA and explained that the FDA held a meeting for Zulresso, and consider zuranolone "is an oral therapy, not the IV therapy . . .[,] we expect that they may ask for the same thing."

241. In response to a question regarding the durability of zuranolone, Defendant Robichaud stated:

> That's a fantastic question and one that we've evolved and learned as we've developed the molecule as well. We believe that patients don't want to be treated forever. You don't think of a depressed patient is now a press patient for life. We believe that depression is a disease, not who you are. What we found out through our clinical studies has been pretty consistent through all the clinical studies that we've conducted, is that a 2-week therapy of this in the vast majority of patients is all that is necessary to put their depression in some phase of remission, bring them to some level of relief from their depression. Will patients go back into depression, that possibility always exists.
>
> Because of that question, we started a very complicated and very thorough clinical study called SHORELINE, which is a study that looks at if patients need to be redosed over the course of a year. And we allowed patients to be doses many times as necessarily during the course of the year. And we'll probably talk about it more in depth. But in general, patients in that entire clinical study required only 1 or 2 doses over the course of an entire year. So it's obvious to us that patients don't want to be treated chronically for a year, 2 years or longer on therapy, especially therapies with side effect profiles that aren't necessarily attractive to most patients. And what we found out in that study is they don't need to be. The vast majority of patients require 1 or 2 doses or dose regimens of the 2 therapy.

242. Defendant Benecchi added that zuranolone had the potential to resolve depressive

episodes as quickly as "within 3 days" for some patients, while offering other patients long-term benefits without "perpetual therapy":

> There are patients that are incredibly troubled by their MDD and they're looking for solutions. And for many patients, sometimes that solution is something that they can take and they can know within 3 days or so that the medication is going to deliver what they want.
>
> In other cases, it's to have the efficacy and to really experience it without the stigmatizing side effects associated with other therapies like sexual dysfunction and weight gain. And sometimes, as Al mentioned, it's the opportunity to take a therapy to experience the relief and then not need to redose or retake the therapy for an extended period of time so they can get back to living the lives that they want to live in the absence of needing perpetual therapy.

243. Defendant Benecchi further stated:

> There's been a lot of sameness in this space and the mentality has been treated to fail. The opportunity to send someone home with a product that they know in 3 days works, and that they can take over a short course that has lasting effect, as Al mentioned, with respect to the SHORELINE data with 80% of patients effectively being able to go 1 year, which has 2, 2-week courses without the tolerability profile that you see with other therapies like sexual dysfunction and weight gain. It's a profound game changer for them.

244. Defendant Benecchi then discussed the potential market for zuranolone, characterizing it as "incredibly large" and estimating the number of "unresolved" patients with MDD, a subset of those with MDD, at 6.8 million, compared to just 500,000 women with PPD.

245. With respect to SAGE-718, Defendant Robichaud touted its efficacy and distinguished it from its competitors, stating:

> We've initiated a very thorough clinical examination of the effects of SAGE-718 in a number of different diseases associated with cognitive impairment, beginning with Huntington's disease, looking at Parkinson's disease as well as Alzheimer's disease. And just—I can briefly say that we've done open label studies in all of those diseases, and we've shown the effects of 718 on those 3 different diseases.
>
> And what we're seeing, thankfully, is a very similar effect on executive function and cognitive performance that is very much unlike what a lot of other companies are looking at today. We're looking at improving synaptic function and we're looking at improving the brain circuitry associated with cognitive decline. What

> we're seeing in a very short amount of time is improvements in, as I said, executive function and cognitive performance. That really encourage us about the utility of this molecule, not just any specific type of neurogenic disease but across a platform of diseases that have cognitive impairment as sort of a common alloy amongst them.

246. On June 1, 2022, the Company issued a press release and hosted a conference call, announcing positive results from the SKYLARK study of zuranolone in PPD. During the call, an analyst noted that "the MDD opportunity is substantially larger than PPD" and asked how the results from the SKYLARK study might "impact the probability of zuranolone approval in MDD." Defendant Greene responded by highlighting the Company's interactions with the FDA, which "confirmed that with a positive WATERFALL [study], we had a fileable package for MDD," adding that "the agreement with the agency was to move ahead with a rolling submission for MDD, . . . include the CORAL data, . . . [and] then [make] an associated NDA filing with the PPD data."

247. In response to a question regarding why the Company was "seeing a larger effect" in zuranolone's treatment of PPD, compared to MDD, Defendants Greene and Doherty denied that there was a difference. Specifically, Defendant Greene stated that "we are seeing consistency of data in both PPD and MDD across 3,000 treated patients," and Defendant Doherty claimed that "[t]he only difference is really in the triggering," explaining that, with respect to PPD, "it's the changes in physiology associated with parturition and birth where it's going to be more variable in MDD."

248. On June 8, 2022, Defendants Greene, Benecchi, and Iguchi participated at the Jefferies Healthcare Conference on behalf of Sage. At the conference, the host observed that "[y]ou guys have always been very confident that you're going to get approval" and asked about the Company's "interactions with the FDA" and what "makes you feel very confident that you're aligned in terms of the path forward for this medication." In response, Defendant Greene stated:

> I think we've been working with the FDA, as you pointed out, significantly through these process even from the days when we were trying to move [Zulresso] forward spoke with the FDA very early about this approach to treating depression and the difference between the standard of care that exists today, a rapid onset, short duration treatment and durability of effect. And they've been very excited about working with us to allow us to at least get the studies needed to demonstrate that and ultimately bring the data forward that would convince them this actually is a differentiated product. So it's been, I would say, I've worked at large pharma companies and has been very different from my experience in those avenues where the FDA is encouraged or really wanted to work with us. And the CORAL study came out of discussions with the FDA about what to do and how we wanted the use case scenario. So they've been working very closely with us to help us think about gathering all the data necessary to inform patients, caregivers and physicians, but how this dose—how this drug could be use in depression and postpartum depression. And that's been our goal ever since and that's why we've done all these different studies with these different end points is to try and give as much data as possible to inform how to treat depression in a way that is very different, that's been done for the last several decades.

249. The host then questioned how "the FDA interpreted" the data from the CORAL study, referencing the Company's decision to unexpectedly change the primary endpoint from Day 15 to 3. In response, Defendant Greene maintained that "the real goal of the CORAL study was to demonstrate rapid onset" when administering zuranolone with another antidepressant, "so the 3-day endpoint was really meant to demonstrate that and very robustly did."

250. On June 13, 2022, Defendant Greene participated at the Goldman Sachs Annual Global Healthcare Conference on behalf of Sage. Defendant Greene first discussed the Company's announcement earlier that day that it would submit a single NDA seeking approval of zuranolone for MDD and PPD instead of first seeking approval for MDD and then PPD. Defendant Greene explained that "accelerat[ing] the PPD aspect of the NDA . . . simplifies the review process," which is "better for us" and "the agency." Defendant Green elaborated, stating that "by combining MDD and PPD, we strengthened the totality of data, particularly given how strong the SKYLARK study was," adding that the decision to file a single NDA "greatly strengthens the overall package and kind of the timely probability of approval by having a totality of the data."

251. Later during the conference, Defendant Greene again attempted to distinguish zuranolone from existing antidepressants, stating that the Company's drug "works particularly well in a group of patients where standard of care doesn't work that well . . . that's with MDD with elevated anxiety or as sometimes they're called anxious depression . . . those patients act a lot like the PPD patients."

252. With respect to the possibility of the FDA choosing not to hold a AdComm meeting for zuranolone, Defendant Greene stated that "they could decide that given the unmet need and given the benefit risk, then AdComm is not warrant[ed] to move forward for approval," adding that, if the FDA did hold a meeting, it would ask if the "onset of action [is] fast" and about "the durability of effect."

253. The statements identified above, issued by the Individual Defendants at the Jefferies Healthcare Conference and the Goldman Sachs Annual Global Healthcare Conference, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. Further, statements that "combining MDD and PPD . . . strengthened the totality of [the] data, particularly given how strong the SKYLARK study was" were materially misleading, because the SKYLARK study in PPD did not demonstrate efficacy or durability in MDD. More broadly, the two conditions are distinct and require distinct treatments. Accordingly, results from the SKYLARK study in PPD could not overcome shortcomings in the Company's data regarding the use of zuranolone in the treatment of MDD.

254. On August 2, 2022, Sage issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's second quarter 2022 financial results (the "2Q22 Press Release"). The same day, Sage filed a quarterly report on Form 10-Q with the SEC for its second quarter of 2022 (the "2Q22 10-Q") and held a related earnings call (the "2Q22 Earnings

Call").

255. The 2Q22 10-Q stated the following with respect to Auvelity:

> In April 2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which had previously received Breakthrough Therapy designation for MDD, but the expected Prescription Drug User Fee Act target action date of August 2021 has been delayed. In May 2022, Axsome announced that it anticipated potential FDA action on its NDA in the second quarter of 2022, which has not been updated.

256. The 2Q22 Press Release quoted Defendant Greene as stating that, "[b]ased on the consistent clinical profile of zuranolone, we believe it has the potential, if approved, to address the significant unmet need for people suffering from MDD and PPD and we are working with a sense of urgency toward our goal of bringing zuranolone to them."

257. During the 2Q22 Earnings Call, Defendant Greene repeated that "the totality of the data generated with zuranolone support [its] potential . . . as a rapidly acting generally well-tolerated oral therapeutic to treat" MDD and "PPD with sustained effect." Defendant Robichaud added that results from the SHORELINE study "support our belief that zuranolone can have remarkable durability" and stated that for patients retreated with zuranolone in the SHORELINE study, "efficacy and safety outcomes were similar to those observed in the initial treatment course."

258. Defendant Greene then stated that the Company decided to terminate the RAINFOREST study "in conjunction with the [FDA]," but would still include data from the RAINFOREST and REDWOOD studies in the NDA. In response to a question regarding his confidence in the Company's regulatory pathway, Defendant Greene stated that "we feel very good about . . . the traction we have with the agency. . . . I would say we're highly confident in the interactions we've had with FDA, stemming back to 2020 when we outlined the LANDSCAPE and NEST programs. We've confirmed multiple times with the agency, the totality of the data

required for [the] NDA filing."

259. Defendant Greene then represented that "there's regular interactions and updates with the FDA . . . formal and then the informal kind of e-mail interactions . . . and things are going well." With respect to whether the FDA would hold an AdComm meeting for zuranolone, Defendant Greene stated that "[i]f they don't want an AdComm and it signals speed of approval, that would be great."

260. On August 9, 2022, Defendants Iguchi, Robichaud, and Benecchi attended the Wedbush PacGrow Healthcare Conference on behalf of Sage. Defendant Robichaud represented that "it has been consistent with all of our studies that zuranolone . . . improv[es] sleep in a lot of patients," characterizing the drug's "beneficial effects on sleep architecture" as a "major side-effect" that was favorable for patients suffering from depression.

261. The following day, Defendants Iguchi, Robichaud, and Benecchi attended the Canaccord Genuity 42nd Annual Growth Conference on behalf of Sage. After the conference, Canaccord issued a report, stating that Sage was "confident on [its] regulatory strategy" for zuranolone, adding that "Sage appears very confident around its filing strategy for [zuranolone]," leading to the conclusion that Sage "is significantly undervalued solely on the zura opportunity in MDD/PPD," with "no specific contribution from" other drugs in the development pipeline.

262. On August 19, 2022, Axsome announced that it had secured FDA approval for Auvelity for use in the treatment of MDD in adults, stating that Auvelity "is the first and only rapid acting oral medicine approved for the treatment of MDD with labeling of statistically significant antidepressant efficacy compared to placebo starting at one week" and "sustained at all subsequent timepoints." Axsome further announced that Auvelity "was statistically significantly superior to placebo in improvement of depressive symptoms as measured by the change in the [MADRS] . . .

total score at Week 6," the "primary endpoint" of the drug's GEMINI study. Axsome stated that Auvelity "uses the first new oral mechanism of action in more than 60 years for MDD."

263. On September 12, 2022, Defendant Greene attended the Morgan Stanley Global Healthcare Conference. Defendant Greene reiterated that if the FDA doesn't "do an AdComm and that represents a more speedy approval, that would be great." Defendant Greene further compared zuranolone to Auvelity, claiming that Auvelity "highlights a profile like zuranolone."

264. When asked by the host whether Auvelity "approval changes your view on the commercial potential for, or positioning of zuranolone at all," Defendant Greene stated:

> It doesn't. And I applaud [Axsome] for getting the drug approved. More options for patients are great. What [Axsome] to me signifies is yet another drug in the wave of getting patients better fast is good. They claim that patients are better in 1 to 2 weeks, which is fantastic, rather than waiting 6 to 8 weeks to get better. And we've already talked about this. The world of whether it's esketamine or psychedelic, get someone better fast without chronic treatment. But they had to get better fast. So I think it highlights a profile like zuranolone, which has been consistent now in 4,000 patients were more where after 2 evening doses of zuranolone, you feel better, take it for 2 weeks, get off drug, not wean off drug, stop drug and you feel better for long periods of time. The short line data, the largest natural study run is a good support of what this drug could do.
>
> That to me represents how the drug probably will behave in the real world, which is kind of an 80% response rate. And for those that responded, the majority didn't need another 2 weeks of drug for the full calendar year that we followed them, 80% required only 1 or 2-week course of treatment in the course of the year. So if you ask anybody living with depression, if they'd rather have 2 or 4 weeks of drug versus 365 days of drug, the answer is pretty self-evident.

265. It was materially misleading for Defendant Greene to suggest that Auvelity "highlights a profile like zuranolone," implying that Auvelity's approval paved the way for approval of zuranolone. In reality, Auvelity's approval posed a significant threat to zuranolone's regulatory pathway and commercial prospects, including because Auvelity's approval lessened the need for another drug designed for the same purposes, particularly one that demonstrated inferior results with respect to both long-term efficacy and safety.

266. On November 8, 2022, Sage issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's third quarter 2022 financial results (the "3Q22 Press Release"). The same day, Sage filed a quarterly report on Form 10-Q with the SEC for its third quarter of 2022 (the "3Q22 10-Q") and held a related earnings call (the "3Q22 Earnings Call").

267. In the 3Q22 10-Q, the Company continued to broadly discuss Auvelity without disclosing the substantial risk related to its FDA approval:

> In August 2022, Axsome Therapeutics, Inc. announced that the FDA had approved AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with an FDA-approved antidepressant affecting norepinephrine and dopamine, bupropion, for the treatment of MDD in adults.

268. During the 3Q22 Earnings Call, Defendant Doherty highlighted "the effectiveness and durability seen in our clinical trials in patients who are on zuranolone," specifically mentioning the SHORELINE study and noting that "zuranolone was generally well tolerated with safety profile seen in the SKYLARK and SHORELINE studies consistent with prior clinical studies." Defendant Greene similarly stated that "[i]n meeting with the FDA, we agreed that the SHORELINE Study could serve as an understanding of long-term safety and retreatment needs."

269. Also during the 3Q22 Earnings Call, Defendant Greene maintained that the FDA deciding not to convene an AdComm could signal early approval, stating that "[i]f the FDA decides not to have an AdComm as a signal of an earlier approval, we're certainly ready for that."

270. On December 6, 2022, Sage issued a press release and hosted a conference call, announcing completion of the rolling submission of the NDA for approval of zuranolone (the "December 6, 2022 Press Release" and the "December 6, 2022 Analyst Call").

271. During the December 6, 2022 Analyst Call, the Individual Defendants failed to correct or address statements issued by a Biogen executive that "there have been no signals of

suicidal ideation or symptoms of withdrawal" from zuranolone. Further, Defendant Benecchi claimed that "it's clear from the LANDSCAPE and NEST programs that the frequency of [adverse events] does drop after the dosing period ends," citing SHORELINE as support for the idea that retreated patients experienced "a reduction in frequency reported following a second or third dosing."

272. Defendant Doherty then claimed that "[w]e're actually very confident in the sustained and durable profile of zuranolone," citing "the LANDSCAPE and NEST program[s]" as support. Defendant Benecchi later reiterated that a single NDA for MDD and PPD "makes it a little more efficient for" FDA review, adding that "we're very confident in the single filing approach."

273. On January 9, 2023 Sage published a presentation for use at the 41st Annual J.P. Morgan Healthcare Conference set to take place the following day. The presentation included a slide, which stated that zuranolone demonstrated "[s]ustained effects [which] lasted beyond [the] completion of treatment[.]"

274. On February 6, 2023, the Company issued a press release, filed on a current report on Form 8-K with the SEC, announcing that the FDA had granted "priority review" of zuranolone for MDD and PPD and explaining that "Priority Review is granted by the FDA to applications for medicines that, if approved, would provide significant improvements in the effectiveness or safety of the treatment, diagnosis, or prevention of serious conditions." The press release further stated:

> The zuranolone NDA includes data from the LANDSCAPE and NEST clinical development programs as well as a Phase 2 study of zuranolone completed by Shionogi in Japan in adults with MDD. The LANDSCAPE program includes five studies of zuranolone in adults with MDD (MDD-201B, MOUNTAIN, SHORELINE, WATERFALL, and CORAL). The NEST program includes two studies of zuranolone in adult women with PPD (ROBIN and SKYLARK).

275. On February 16, 2023, the Company issued a press release, filed on a current report

on Form 8-K with the SEC, reporting on the Company's fourth quarter and full year 2022 financial results (the "FY22 Press Release"). The same day, Sage hosted a related earnings call (the "FY22 Earnings Call") and filed its 2022 annual report on Form 10-K with the SEC (the "2022 10-K"), which was signed by Defendants Greene, Iguchi, Jonas, Cola, Paul, Starr, Frates, Germano, Barrett, and Golumbeski.

276. The 2022 10-K stated the following with respect to Auvelity:

> If approved, zuranolone may also face competition for the treatment of MDD from AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with bupropion, an FDA-approved antidepressant affecting norepinephrine and dopamine, which such combination formulation was approved in August 2022 by the FDA for the treatment of MDD in adults.

277. The FY22 Press Release quoted Defendant Greene as stating that, with respect to the Company's "NDA filing for zuranolone in MDD and PPD" and "promising and targeted pipeline, . . . this momentum puts us in a position of strength as we kick off 2023." The FY22 Press Release further stated that "[z]uranolone, if approved, could represent the first oral, short course (14-day) medication with rapid onset for MDD and PPD."

278. During the FY22 Earnings Call, Defendant Doherty touted zuranolone's "rapid and sustained reduction in depressive symptoms as early as 2 or 3 days" and "generally well-tolerated safety profile." Defendant Benecchi similarly stated that "the opportunity in MDD is large with millions of patients not satisfied with current treatment options," citing zuranolone's purported rapidity and durability:

> This is why rapidity matters, both in terms of initiating a therapy as soon as patients show symptoms, as well as achieving the rapid improvement of depressive symptoms. The key takeaway here is a more rapid and sustained approach to treating a depressive episode may increase the likelihood of better symptomatic and functional outcomes. Given the rapid improvements seen in clinical trials to date, we believe that, if approved, zuranolone has the potential to provide a new treatment option to patients suffering with MDD, with the goal of helping them return to a state of well-being sooner.

279. Defendant Benecchi further claimed that, "[g]iven the unmet need, we believe that zuranolone, if approved, is best positioned at launch for MDD patients requiring a first add or first switch therapy after continuing to experience depressive symptoms, following their initial treatment course, including patients who have tolerability issues or noncompliance with chronic therapy." Defendant Benecchi continued, stating that "there's a high understanding of unmet need in and amongst the payers, and truly a perception that they need something that works quite differently than what they've seen historically."

280. During the FY22 Earnings Call, Defendant Greene again stated that "[i]f the FDA decides not to hold an AdComm and that's a signal of a faster approval, we like that too."

281. On March 6, 2023, Defendant Greene attended the Cowen Health Care Conference and repeated that "if [the FDA doesn't] do an AdComm as a signal of a rapid approval or even early approval, we'll take that too, and we'll be prepared to launch." At the conference, Defendant Greene further stated:

> [T]there's a senior team that's been consistent from the beginning with us, that's been engaged.
>
> And even before I started as CEO, I read every regulatory communication. What I can say is all of the regulatory communications and minutes have been consistent from day 1. The FDA was really helpful with Sage designing the landscape in these programs and talking about the Phase IIIs.
>
> They were very helpful in helping to understand one of the Phase IIIs that was designed in REDWOOD that didn't need to get run based upon the SHORELINE data. So the communication with senior levels, medical reviewers and others has been consistent from the beginning.

282. The statements identified above, issued by the Individual Defendants between November 8, 2022 and March 6, 2023, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. Specifically, the

Individual Defendants continued to overstate the efficacy and durability of zuranolone, including with Defendant Benecchi's statements, touting the drug's purportedly "more rapid and sustained approach to treating a depressive episode." Further the Individual Defendants misleadingly represented that the FDA's decision not to hold an AdComm could indicate faster approval.

283. On March 8, 2023, the Company announced that the FDA would not convene an AdComm for zuranolone's NDA. Due to the Individual Defendants' prior statements, this announcement signaled to the market that FDA approval could come earlier.

284. On March 29, 2023, Defendants Iguchi, Benecchi, and Doherty attended the 2023 Stifel CNS Days Conference on behalf of Sage. At the conference, the host expressed "surprise[] that there's not an AdComm," stating that "that's certainly a good thing. No AdComm, no priority review is usually great," before asking Defendant Doherty if he was surprised. In response, Defendant Doherty claimed that "they've decided in this case that they don't need to convene an expert group of panelists from the outside."

285. During the conference, Defendant Benecchi highlighted the market opportunity for zuranolone, consisting of "about 6.5 million people with MDD who are actively making treatment changes in a given year," adding that "the vast majority of those have failed one or more existing antidepressants." Defendant Benecchi further discussed the "nearly 500,000 or so moms or one in eight live births, women that are suffering with PPD who very much acutely need something immediately that can help them get back on a course to well-being." Defendant Benecchi explained that Sage's "ambition with zuranolone in MDD is to be the first data or first switch medication for those that are suffering with MDD" and the "first-line therapy" for women with PPD.

286. In response to a question regarding Auvelity, Defendant Benecchi failed to mention zuranolone's competitor and stated that "zuranolone has shown itself to be a versatile therapy,

either as monotherapy, as an adjunctive therapy, or as a therapy that can be co-initiated with other antidepressants."

287. On April 27, 2023, Sage filed a proxy statement on Form DEF 14A with the SEC (the "2023 Proxy"), soliciting shareholder approval for, *inter alia*, the re-election of Defendants Cola, Greene, Jonas, and Federer to serve for another three-year term on the Company's Board and the compensation of certain of the Company's executive officers, including Defendants Greene, Iguchi, Benecchi, Gault, and Robichaud.

288. The 2023 Proxy reported:

> In 2022, we achieved multiple development milestones evaluating SAGE-718, including:
>
> - commencement of the placebo-controlled Phase 2 DIMENSION Study and Phase 2 SURVEYOR Study, and the open-label Phase 3 PURVIEW Study of SAGE-718 in patients with Huntington's disease cognitive impairment;
>
> - announcement of additional results from the open-label Phase 2 PARADIGM Study and commencement of the placebo-controlled PRECEDENT Study in patients with mild cognitive impairment due to Parkinson's disease; and
>
> - commencement of the placebo-controlled Phase 2a LUMINARY Study in patients with mild cognitive impairment and mild dementia due to Alzheimer's disease.

289. With respect to the Company's internal controls and legal and regulatory compliance the 2023 Proxy stated that "the Audit Committee operates under a written charter approved by the Board of Directors, which provides that its responsibilities include the oversight of the quality of our financial reports and other financial information and our compliance with legal and regulatory requirements" and "reviewing with management and our independent registered public accounting firm the adequacy of our internal controls over financial reporting."

290. With respect to the Company's risk assessment and risk management functions, the

2023 Proxy stated:

> Our Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board of Directors performs this oversight role by using several different levels of review. In connection with its reviews of our operations and corporate functions, our Board of Directors addresses the primary risks associated with those operations and corporate functions. In addition, our Board of Directors reviews the risks associated with our business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies. The Board of Directors also evaluates from time to time the processes by which our exposure to risk is assessed and managed by management.
>
> Each of the committees of our Board of Directors also oversees the management of our risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors.

291. On May 2, 2023, Sage issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's first quarter 2023 financial results (the "1Q23 Press Release"). The same day, Sage filed a quarterly report on Form 10-Q with the SEC for its first quarter of 2023 (the "1Q23 10-Q") and held a related earnings call (the "1Q23 Earnings Call").

292. The 1Q23 10-Q stated the following with respect to Auvelity:

> If approved, zuranolone may also face competition for the treatment of MDD from AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with bupropion, an FDA-approved antidepressant affecting norepinephrine and dopamine, which such combination formulation was approved in August 2022 by the FDA for the treatment of MDD in adults.

293. During the 1Q23 Earnings Call, Defendant Greene explained that "during [zuranolone's] review period, we'll not be making detailed comments on the potential label, FDA interactions or other related topics for zuranolone." Despite this, Defendant Doherty stated that "physicians continue to highlight that the potential to achieve both a rapid and sustained effect matters deeply to them and remains critical to their patients" and claimed that zuranolone met that need. Defendant Doherty further stated that Sage has "received consistent feedback on what they

consider the main strengths of the zuranolone clinical data," with "rapid onset of action seen in clinical trials" and "an improvement in depressive symptoms observed as early as day 3. . . . Physicians note that this clinical profile has the potential to be particularly impactful if zuranolone is approved, given zuranolone's 14-day oral course of treatment."

294. Later during the 1Q23 Earnings Call, Defendant Gault stated that, "as a clinician that's treated patients with depression, the thing that really strikes me about the zuranolone data is the rapidity of the response and the durability of that response. . . . It's my lead proposition that zuranolone will be used as an add-on ahead of any atypical antipsychotics."

295. In response to a question regarding recent competitor launches, Defendant Greene stated that "we are paying close attention to all the new launches, whether it's migraine launches or depression launches. And we are grabbing a whole bunch of learnings from those." Defendant Benecchi echoed this sentiment, specifically referencing Auvelity:

> [A]s you take a step back and you think about the launches, we pay, as Barry said, very close attention to all facets from the way that they target their customers, the size of the sales force, the tools and resources that they're using to effectively manage their launch all the way through to external media and how they're spending their media dollars. So, we have quite a close lens trained on the various competitors and how they're acting in the market.
>
> What I would take a step back and say is that the approval and initial use of other products is really an encouraging signal that both patients and clinicians are really looking for therapies that work. In the case of Axsome's product, it's a therapy that they are looking at because it has a new mechanism of action and works a little bit faster than maybe some of the other medications that have historically been available in the market for the last 30 years to 35 years. I think this really demonstrates that there's unmet need for new treatment options for the management of MDD. As you know, there still is no treatment, an orally available treatment for PPD, and there is significant need there for a product like zuranolone.

296. Also during the 1Q23 Earnings Call, Defendant Greene explained that, if zuranolone secured approval, the Company would aim to "stay below [the] specialty tier" at "roughly around $10,000 per patient per year" for a 14-day treatment.

297. The statements identified above, issued by the Individual Defendants on May 2, 2023, were materially false and misleading for many of the same reasons that the Individual Defendants' previous statements were misleading. Specifically, the Individual Defendants continued to misleadingly represent that zuranolone was well-positioned to secure FDA approval despite insufficient data to demonstrate its durable efficacy. The Individual Defendants overstated the efficacy of zuranolone and misrepresented the results of the Company's studies, including by highlighting the purported "rapidity of the response and the durability of that response" associated with the treatment.

298. On May 10, 2023, Defendants Robichaud, Benecchi, and Iguchi attended the BofA Securities 2023 Health Care Conference on behalf of Sage. During the conference, Defendant Robichaud responded to a question regarding the FDA deciding not to convene an AdComm by stating that "[a]s we had indicated in the past, we were agnostic to it . . . we look at it as sort of an affirmation that the data set that we've compiled and submitted to the agency has given them a sufficient data in order for them to review the drug and make a determination of whether not the drug should be approved or not."

299. On May 17, 2023, at the RBC Capital Markets Global Healthcare Conference, Defendant Robichaud addressed the FDA review process and stated that "everything is going according to plan . . . things are going well with them . . . we don't see any problems right now." Defendant Robichaud further stated that, "over the years of developing zuranolone from our early days, we've been working with the agency to create the LANDSCAPE and NEST programs around MDD and PPD, respectively, to allow us to gain the dataset that we always thought would be necessary for the industry review to be able to decide on whether or not to approve this drug . . . we're working very closely with [the FDA]."

300. The statements identified above, issued by the Individual Defendants at the conferences on May 10 and May 17, were materially misleading because the Individual Defendants continued to conceal the issues related to zuranolone securing FDA approval for use in the treatment of MDD.

301. On June 12, 2023, at the Goldman Sachs's 44th Annual Global Healthcare Conference, Defendant Greene touted zuranolone's rapid onset and efficacy, stating that "[a]fter 2 oral doses at night, those that respond report starting to feel better" and "then at day 14, those who respond continue to stay well." Defendant Greene stated that the "unmet need is clear" and "[t]he unique product profile of zuranolone if approved in MDD and PPD is unique for them." Defendant Greene further repeated that Sage sought to price zuranolone "roughly under $10,000 per patient per year."

302. On July 25, 2023, Biogen issued a press release announcing its financial results for the second quarter of 2023 and hosted a related earnings call. Analysts observed that Biogen had deviated from prior fiscal periods by failing to mention zuranolone in its press release or related earnings call. As a result of the resulting uncertainty surrounding zuranolone, the price of Sage stock declined 21% over several days, from a close of $43.95 per share on July 24, 2023 to a close of $34.68 per share on July 31, 2023.

303. On August 4, 2023, Sage issued a press release, announcing the FDA's approval of zuranolone for use in the treatment of PPD only. The Company disclosed that the FDA issued a Complete Response Letter ("CRL"), denying approval of zuranolone for use in the treatment of MDD and advising that additional studies were required to demonstrate its efficacy. Specifically, the Company disclosed that "[t]he CRL stated that the application did not provide substantial evidence of effectiveness to support the approval of zuranolone for the treatment of MDD and that

an additional study or studies will be needed."

304. On August 7, 2023, Sage issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's second quarter 2023 financial results (the "2Q23 Press Release"). The same day, Sage filed a quarterly report on Form 10-Q with the SEC for its second quarter of 2023 (the "2Q23 10-Q") and held a related earnings call (the "2Q23 Earnings Call"). In the 2Q23 Press Release and during the 2Q23 Earnings Call, the Individual Defendants provided further context surrounding the FDA's denial of approval of zuranolone for use in the treatment of MDD, revealing that the Company's NDA for MDD likely lacked sufficient evidence to demonstrate durability.

305. On this news, the price of Sage stock declined a staggering 53.6% over three days, from a close of $36.10 per share on August 4, 2023 to a close of $16.75 per share on August 7, 2023.

306. On August 31, 2023, Sage announced that it would be implementing a "strategic reorganization," involving a 40% workforce reduction and a change in the Company's leadership structure which included the departure of Defendants Robichaud and Doherty.

307. The same day, RBC issued a report, providing further information regarding the FDA's review of zuranolone, which disclosed, *inter alia*, that: (i) the use of zuranolone for the treatment of MDD was associated with side effects including extreme sedation, with multiple patients reportedly being rendered unconscious, and an increased rate of suicidality; (ii) "the FDA's characterization of the [adverse effect] profile does not appear completely aligned with SAGE's historical interpretations," meaning the Individual Defendants misrepresented information related to the safety of the drug; and (iii) the "FDA seemed to suggest an AdComm was never considered because the drug was not first-in-class and there were no scientific/technical

issues that would benefit from an AdComm discussion."

308. With respect to the incidences of suicidal ideation, the FDA review materials clarified that the SHORELINE study, designated as 217-MDD-303, demonstrated the following:

> In Study MDD-303A, on-treatment, five subjects reported SI, two subjects reported suicide attempts (one of these subjects was also among the five who reported an SI AE), and one subject reported suicidal behavior; off-treatment, four subjects reported SI, two subjects reported suicide attempt, two reported intentional self-injury, and one reported suicidal behavior. In Study MDD-303B, one subject reported on-treatment suicide attempt and one subject reported off-treatment SI.

309. On September 13, 2023, at the Morgan Stanley 21st Annual Global Healthcare Conference, Defendant Greene stated that, "when orally taken SAGE-718 dramatically increases cognition in a very rapid period of time" and that SAGE-324 effectuated "change in tremor amplitude," with benefits through 28 days at the maximum daily dose of 60 mg." Defendant Greene further stated that the pricing for zuranolone in treating PPD would rise above previously stated levels, explaining that "previously, we highlighted that with MDD and PPD, that $10,000 was the ceiling specialty tier," but "I would not consider that on the table right now."

310. On September 20, 2023, at the T.D. Cowen 3rd Annual Novel Mechanisms in Neuropsychiatry Summit, Defendant Gault stated that, with respect to SAGE-718, the Company was conducting three studies, adding that "the primary endpoint" for the DIMENSION Study "is the Huntington's Disease Cognitive Assessment Battery, which is a battery of a number of different cognitive tests that test learning and memory" to gauge change in function, but "hasn't been validated from a regulatory perspective."

311. The statements identified above, issued by the Individual Defendants during the conferences on September 13 and September 20 were materially misleading because representations that "SAGE-718 dramatically increases cognition in a very rapid period of time," and that SAGE-324 effectuated "change in tremor amplitude" with benefits through 28 days, failed

to disclose limitations with the Company's study methodologies. Indeed, Defendant Gault acknowledged that Sage had adopted a primary endpoint for a study of SAGE-718 that was not "validated from a regulatory perspective."

312. On October 18, 2023, the Company announced that the FDA had granted SAGE-718 Orphan Drug Designation, stating that "[m]ultiple clinical studies are ongoing with SAGE-718 across several disease areas."

313. On November 7, 2023, Sage issued a press release, filed on a current report on Form 8-K with the SEC, reporting on the Company's third quarter 2023 financial results (the "3Q23 Press Release"). The same day, Sage filed a quarterly report on Form 10-Q with the SEC for its third quarter of 2023 (the "3Q23 10-Q") and held a related earnings call (the "3Q23 Earnings Call").

314. In the 3Q23 Press Release, the Company announced that the wholesale acquisition cost of zuranolone for PPD was $15,900 for a full 14-day treatment course, significantly above the $10,000 cost that the Company had previously announced. During the 1Q23 Earnings Call, Defendant Benecchi stated that the cost of zuranolone for PPD was "within the annual wholesale acquisition range of other commonly prescribed branded medications used to treat brain health disorders."

315. On January 8, 2024, at the 42nd Annual J.P. Morgan Healthcare Conference, Defendant Greene stated that, with respect to SAGE-718, the Company had five "clinical studies up and running this year with four top line data readouts," and, with respect to SAGE-324, "what we saw with KINETIC, as we saw at a 60-milligram dose, we saw significant clinically meaningful and statistically significant change in tremor amplitude."

316. On February 14, 2024, the Company issued a press release, filed on a current report

on Form 8-K with the SEC, reporting on the Company's fourth quarter and full year 2023 financial results (the "FY23 Press Release"). The same day, Sage hosted a related earnings call (the "FY23 Earnings Call") and filed its 2023 annual report on Form 10-K with the SEC (the "2023 10-K"), which was signed by Defendants Greene, Iguchi, Jonas, Cola, Paul, Frates, Germano, Barrett, Golumbeski, and Federer. The 2023 10-K stated the following with respect to Auvelity:

> Zuranolone, if approved in the future for the treatment of MDD, may also face competition from AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with bupropion approved for the treatment of MDD in adults.

317. During the FY23 Earnings Call, Defendant Greene stated that, with respect to SAGE-718's testing, "[w]e really are excited by the progress" and "excited to have readouts for both Huntington's, Parkinson's and Alzheimer's this year." Defendant Gault then stated that "we will take what we learned from [SAGE-718's] SURVEYOR study and make a decision about what the proper endpoints should be for DIMENSION . . . we have no reason to believe that th[e] endpoint will not be appropriate or sufficient."

318. On March 5, 2024, at the T.D. Cowen 44th Annual Healthcare Conference, Defendant Gault responded to a question regarding whether the FDA would "buy into" the use of the TETRAS scale for SAGE-324's studies by stating that it is "a good measure to use for signal detection."

319. On March 19, 2024, Defendant Greene attended the Stifel Virtual CNS Days conference on behalf of Sage. During the conference, the host questioned the Company's use of the Huntington's Disease Cognitive Assessment Battery, (or HD-CAB), in its SAGE-718 studies, stating that "[a]nother company in the space basically got feedback from the FDA that they didn't like this measure only a couple years ago" and asking, "why rely on this scale and why not try to look at something else or get better regulatory alignment ahead of time." In response, Defendant

Greene explained that "[w]e have seen good regulatory flexibility in orphan diseases and particularly something here where there's nothing for people suffering from cognitive issues in Huntington's disease" and "we think we've got a number of primary, secondary endpoint[s] to demonstrate am effect here," adding that "the regulatory precedence is relevant but our conversations are going well."

320. The host later reiterated that "[t]he measures you guys [are] using, again, don't really have much precedent." In response, Defendant Greene stated, "we're measuring a lot of different cognitive measures at various time points . . . because we know there may be some learning effect[s] with these kinds of studies . . . we'll see what works well, what doesn't work," and "sit down with regulators to map out what the right Phase 3s look like."

321. With respect to SAGE-324, the host asked whether, "from a regulatory perspective," the Company was "comfortable" with the end points and "the way you're adjudicating tremor." In response, Defendant Greene stated that, "yes, there's general alignment . . . with these data in hand, we'll have that discussion."

322. On April 17, 2024, the Company issued a press release, announcing topline results from the Phase 2 PRECEDENT study of SAGE-718, disclosing that the study "did not meet its primary endpoint of demonstrating statistically significant difference from baseline in participants treated with once-daily [SAGE-718] versus placebo on the Wechsler Adult Intelligence Scale Fourth Edition-IV (WAIS-IV) Coding Test score at Day 42. . . . Analyses did not suggest any meaningful differences versus placebo in the other exploratory endpoints such as SCOPA-Cog. . . . Based on the data, the Company does not plan any further development of [SAGE-718] in [Parkinson's Disease]."

323. During an earnings call, hosted by the Company on the same day, Defendants

Greene and Gault addressed the study's failure to meet primary or other endpoints, but Defendant Gault claimed that "we believe these results are not necessarily predictive of the results in our other ongoing studies" and further stated:

> It is important to remember that although cognitive impairment is common across Parkinson's, Huntington's and Alzheimer's diseases, the underlying pathophysiology and symptomatology of these diseases are very distinct. Further, the [SAGE-718] studies differ in terms of indication, patient selection criteria, duration of treatment, sample size and certain endpoints.

324. Defendant Greene echoed that sentiment, stating that "the results we've seen here are not necessarily predictive of the results we'll see in Huntington's and Alzheimer's" and that "the endpoint in the Huntington trials, particularly is very different than the endpoint we saw here."

325. The market reacted negatively to the news surrounding the improperly designed SAGE-718 study. Specifically, the price of Sage stock declined 19.58%, from a close of $15.63 per share on April 16, 2024 to a close of $12.57 per share on April 17, 2024.

326. On April 24, 2024, Sage filed a proxy statement on Form DEF 14A with the SEC (the "2024 Proxy"), soliciting shareholder approval for, *inter alia*, the re-election of Defendants Barrett and Germano to serve for another three-year term on the Company's Board and the compensation of certain of the Company's executive officers, including defendants Greene, Iguchi, Benecchi, Gault, Robichaud.

327. With respect to the Company's internal controls and legal and regulatory compliance the 2024 Proxy stated that "the Audit Committee operates under a written charter approved by the Board of Directors, which provides that its responsibilities include the oversight of the quality of our financial reports and other financial information and our compliance with legal and regulatory requirements" and "reviewing with management and our independent registered public accounting firm the adequacy of our internal controls over financial reporting."

328. With respect to the Company's risk assessment and risk management functions, the 2024 Proxy stated:

> Our Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board of Directors performs this oversight role by using several different levels of review. In connection with its reviews of our operations and corporate functions, our Board of Directors addresses the primary risks associated with those operations and corporate functions. In addition, our Board of Directors reviews the risks associated with our business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies. The Board of Directors also evaluates from time to time the processes by which our exposure to risk is assessed and managed by management.
>
> Each of the committees of our Board of Directors also oversees the management of our risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors.

329. On April 25, 2024, the Company issued a press release, announcing financial results for the first quarter of 2024, which affirmed that the Company did "not plan any further development" of SAGE-718 as a treatment for Parkinson's Disease.

330. During a related earnings call, hosted by Sage on the same day, Defendant Gault repeated the idea that the results from the failed SAGE-718 study were "not necessarily predictive of the results we may see in [] ongoing Huntington's disease and Alzheimer's disease studies" and stated the following regarding the Company's ongoing studies:

> As we said on our call last week, is it is important to remember that these results are not necessarily predictive of the results we may see in our ongoing Huntington's disease and Alzheimer's disease studies, given the very distinct underlying pathophysiology and symptomatology of these diseases. While we're disappointed by the results of the PRECEDENT study, we continue to believe in the potential of [SAGE-718] in the other indications we are studying and look forward to the various data readouts anticipated later this year.

331. With respect to SAGE-324, Defendant Gault referenced "encouraging data" from the KINETIC study.

332. On June 11, 2024, the Company issued a press release, announcing the results of SAGE-718's Phase 2 SURVEYOR study and reporting that "[t]he study met its primary endpoint demonstrating a statistically significant difference as measured by the [HDCAB] . . . composite score at baseline between healthy participants and [those] with Huntington's Disease." The press release quoted Defendant Gault as stating that "[t]he study was not designed or powered to demonstrate a statistically significant difference between [SAGE-718] and placebo" but "[t]here was a small numerical difference observed between [SAGE-718] and placebo on the HD-CAB composite score at Day 28."

333. On June 12, 2024, at the Goldman Sachs Global Healthcare Conference, Defendant Gault stated that SAGE-324 "reduced tremor amplitude," but the 60 mg dose in the morning "wasn't very tolerable." The host of the conference again questioned the Company's use of the TETRAS scale, and Defendant Gault again recognized the FDA's resistance to using TETRAS as an endpoint but nevertheless defended its use:

> [W]e're aware that there has been some regulatory feedback to other sponsors about using the modified ADL. However, when you're trying to learn about how your product works, you want to measure something that is as proximal to its effect as possible. So actually measuring the tremor amplitude is much more proximal than measuring something around activities of daily living down the road.

334. The following day, the Company issued a press release, reporting topline results of the Phase 2 KINETIC 2 study of SAGE-324 for the treatment of essential tremor. The press release revealed that the study "did not demonstrate a statistically significant dose-response relationship in change from baseline to Day 91 based on the primary endpoint, The Essential Tremor Rating Assessment Scale (TETRAS) Performance Subscale (PS) Item 4 (upper limb) total score, in participants with ET [essential tremor] . . . there were no statistically significant differences demonstrated for any dose of SAGE-324 versus placebo in the change from baseline to Day 91 on

the TETRAS PS Item 4 Total Score or the TETRAS Activities of Daily Living (ADL) Composite Score. . . . Given these results, Sage and Biogen will close the ongoing open label safety study of SAGE-324 in ET and do not plan to conduct further clinical development of SAGE-324 in ET."

335. On this news, the price of Sage stock declined 20.64%, from a close of $13.08 per share on July 23, 2024 to a close of $10.38 per share on July 24, 2024.

DAMAGE TO SAGE

336. As a direct and proximate result of the Individual Defendants' misconduct, Sage has incurred, and will continue to incur, losses and expenses amounting to millions of dollars.

337. Such expenditures include, but are not limited to, legal fees associated with defending against the Securities Class Action and any internal investigations, and amounts paid to outside lawyers, accountants, and investigators in connection thereto.

338. These expenditures also include, but are not limited to, the costs associated with implementing measures to remediate the material weaknesses in the Company's internal controls with respect to public disclosures and legal and regulatory compliance.

339. These losses also include, but are not limited to, substantial compensation and benefits paid to the Individual Defendants who breached their fiduciary duties to the Company, such as bonuses linked to the Company's achievement of specific objectives, as well as other benefits provided to those Individual Defendants.

340. As a direct and proximate result of the Individual Defendants' actions, Sage has suffered and will continue to suffer damage to its reputation and goodwill, along with a "liar's discount" that will negatively impact the Company's stock in the future. This is due to the Company's misrepresentations and the Individual Defendants' breaches of fiduciary duties and unjust enrichment.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

341. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties by the Individual Defendants.

342. Sage is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would otherwise not have.

343. Plaintiff is a current shareholder of Sage and was a continuous shareholder of the Company during the period of the Individual Defendants' wrongdoing alleged herein. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights and has retained counsel competent and experienced in derivative litigation.

344. At the time this action was commenced, the seven-member Board was comprised of Defendants Greene, Barrett, Cola, Federer, Frates, Germano, and Golumbeski (the "Director Defendants"). Accordingly, Plaintiff is only required to show that four Directors cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. As set forth below, all of the Board's current directors are incapable of making an independent and disinterested decision to institute and vigorously prosecute this action, including because they face a substantial likelihood of liability, and so demand on the Board to institute this action is not necessary because such a demand would have been a futile act.

345. The Director Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.

346. Each of the Director Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the

Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.

347. Moreover, the Director Defendants willfully ignored, or recklessly failed to inform themselves of, the obvious problems with the Company's internal controls, practices, and procedures and failed to make a good faith effort to correct the problems or prevent their recurrence.

348. Defendant Greene is not disinterested or independent and is therefore incapable of considering a demand because he has served as the Company's CEO since 2020. Furthermore, Defendant Greene is not disinterested or independent because he is named as a defendant, and faces significant personal liability, in the Securities Class Action based on substantially the same wrongdoing as alleged herein, specifically issuing materially false and misleading statements during the Relevant Period.

349. Defendants Barrett, Cola, Federer and Frates served on the Company's Audit Committee during the Relevant Period (the "Audit Defendants") and, pursuant to the Audit Committee Charter, were specifically charged with the responsibility to assist the Board in fulfilling its oversight responsibilities related to, *inter alia*, financial accounting and reporting, the underlying internal controls and procedures over financial reporting, and the audits of the financial statements. At all relevant times, however, the Audit Defendants breached their fiduciary duty to the Company by failing to prevent, correct, or inform the Board of the issuance of material misstatements and omissions regarding the Company's regulatory standing, the safety and efficacy of its products, and the adequacy of its internal controls as alleged above. Therefore, the Audit Defendants cannot independently consider any demand to sue themselves for breaching their

fiduciary duties to the Company, as that would expose them to substantial liability and threaten their livelihoods.

350. The Director Defendants, as members of the Board, were and are subject to the Company's Code of Conduct. The Code of Conduct goes well beyond the basic fiduciary duties required by applicable laws, rules, and regulations, requiring the Directors to also adhere to the Company's standards of business conduct. The Director Defendants violated the Code of Conduct because they knowingly or recklessly participated in making and/or causing the Company to make the materially false and misleading statements alleged herein. Because the Director Defendants violated the Code of Conduct, they face a substantial likelihood of liability for breaching their fiduciary duties, and therefore demand upon them is futile.

351. All of the Board's current members derive substantial revenue from the Company, control the Company, and are indebted to each other. These conflicts of interest have precluded the Board's current members from calling into question the Director Defendants' conduct. Specifically, none of the Board's current members have taken remedial action to redress the conduct alleged herein. For instance, none of the Board's current members have sought to enforce the Company's Clawback Policy, which provides:

> In the event we are required to prepare an accounting restatement due to material noncompliance with any financial reporting requirement under U.S. federal securities laws, including any required restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, it is our policy to recover reasonably promptly the amount of erroneously awarded incentive-based compensation received by Covered Persons. The recovery of such compensation applies regardless of whether an executive engaged in misconduct or otherwise caused or contributed to the requirement for the accounting restatement.

352. The Director Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and

intentional, reckless, or disloyal misconduct. Thus, none of the directors can claim exculpation from their violations of duty pursuant to the Company's charter. As a majority of the directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein. They cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

353. The acts complained of herein constitute violations of fiduciary duties owed by Sage's officers and directors, and these acts are incapable of ratification.

354. The Individual Defendants may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds i.e., monies belonging to the stockholders of Sage. If there is a directors' and officers' liability insurance policy covering the Individual Defendants, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Individual Defendants, known as, inter alia, the "insured-versus-insured exclusion." As a result, if the Director Defendants were to sue themselves or certain officers of Sage, there would be no directors' and officers' insurance protection. Accordingly, the Director Defendants cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Director Defendants is futile and, therefore, excused.

355. If there is no directors' and officers' liability insurance, then the directors will not cause Sage to sue the Defendants named herein, since, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event as well.

356. Thus, for all of the reasons set forth above, all of Sage's current directors are unable to consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

COUNT I
Against the Individual Defendants for Violations of § 14(a) of the Exchange Act and Rule 14a-9

357. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

358. The Individual Defendants violated § 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), and Rule 14a-9, 17 C.F.R. § 240.14a-9, promulgated thereunder by the SEC.

359. The Individual Defendants, individually and in concert, disseminated and/or permitted the dissemination of materially false and misleading statements in 2021, 2022, 2023, and 2024 Proxies. As alleged above, these filings contained materially false and misleading statements concerning the Company's primary drug candidates, its legal and regulatory compliance, and the adequacy of the Company's internal controls and its risk oversight function.

360. The 2021 Proxy was used to solicit shareholder votes in connection with the re-election of Defendants Barrett, Germano, and Paul to the Board. The 2022 Proxy was used to solicit shareholder votes in connection with the re-election of Defendants Frates, Golumbeski, and Starr to the Board. The 2023 Proxy was used to solicit shareholder votes in connection with the re-election of Defendants Cola, Greene, Jonas, and Federer to the Board. The 2024 Proxy was used to solicit shareholder votes in connection with the re-election of Defendants Barrett and Germano

to the Board. Further, these filings were used to solicit the compensation of certain of the Company's executive officers including Defendants Greene, Jonas, Iguchi, Robichaud, Benecchi, and Gault. While the shareholder votes on executive compensation were non-binding, each of the 2021, 2022, 2023, and 2024 Proxies indicated that "the Compensation Committee will carefully consider the outcome of this vote when considering future executive compensation policies and decisions."

361. Describing the Company's "Compensation Philosophy and Objectives," each of the 2021, 2022, 2023, and 2024 Proxies indicated that compensation is performance-based, stating that the "Compensation Committee believes that a well-designed compensation program should align executive interests with the drivers of growth and stockholder returns . . . . As a result, we maintain a strong pay-for-performance orientation in our compensation program."

362. The materially false and misleading statements contained in the 2021, 2022, 2023, and 2024 Proxies regarding the Company's primary drug candidates, its legal and regulatory compliance, and the adequacy of the Company's internal controls and its risk oversight function therefore misleadingly induced shareholders to vote in favor of the election of Defendants Barrett, Germano, Paul, Frates, Golumbeski, Starr, Cola, Greene, Jonas, and Federer and performance-based compensation to Defendants Greene, Jonas, Iguchi, Robichaud, Benecchi, and Gault, to which they were not entitled.

363. The payment of unwarranted performance-based compensation to these Company executives was a waste of corporate assets.

COUNT II
Against the Individual Defendants
For Breach of Fiduciary Duties

364. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

365. The Individual Defendants owed the Company fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

366. The Individual Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

367. The Individual engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Individual Defendants breached their fiduciary duties of loyalty and good faith by permitting the use of inadequate practices and procedures to guide the truthful dissemination of Company news to the investing public and to the Company's shareholders, allowing or permitting false and misleading statements to be disseminated in the Company's SEC filings and other disclosures, and otherwise failing to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

368. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company. As a direct and proximate result of the Individual Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs incurred in defending itself in the Securities Class Action, exposing the Company to millions of dollars in potential class-wide damages in the Securities Class Action, and damage to the share price of the Company's stock, resulting in an increased cost of capital, and reputational harm

369. Plaintiff, on behalf of Sage, has no adequate remedy at law.

COUNT III
Against the Individual Defendants
For Aiding and Abetting Breach of Fiduciary Duty

370. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

371. By encouraging and accomplishing the illegal and improper transactions alleged herein and concealing them from the public, the Individual Defendants have each encouraged, facilitated, and advanced their breach of their fiduciary duties. In so doing, the Individual Defendants have each aided and abetted, conspired, and schemed with one another to breach their fiduciary duties, waste the Company's corporate assets, and engage in the ultra vires and illegal conduct complained of herein.

372. Plaintiff, on behalf of Sage, has no adequate remedy at law.

COUNT IV
Against the Individual Defendants
For Unjust Enrichment

373. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

374. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of Sage.

375. The Individual Defendants were unjustly enriched by their receipt of bonuses, stock options, or similar compensation from Sage that was tied to their performance or to the artificially inflated valuation of Sage.

376. Plaintiff, as a stockholder and representative of the Company, seeks restitution from the Individual Defendants, and seeks an order from this Court disgorging all profits, benefits, and

other compensation obtained by the Individual Defendants as a result of their wrongful conduct and fiduciary breaches.

377. As a direct and proximate result of the Individual Defendants' misconduct, the Company has suffered significant damages, as alleged herein.

378. Plaintiff, on behalf of Sage, has no adequate remedy at law.

COUNT V
Waste of Corporate Assets
Against the Individual Defendants

379. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

380. The Individual Defendants breached their fiduciary duties by failing to properly supervise and monitor the adequacy of Sage's internal controls, by issuing, causing the issuance of, and/or failing to correct the false and misleading statements identified herein, and by allowing the Company to engage in an illegal, unethical, and improper course of conduct, which was continuous, connected, and ongoing at all relevant times.

381. As a result of the misconduct described above, the Individual Defendants wasted corporate assets by, among other things, incurring and paying defense costs in connection with the Securities Class Action, and approving performance-based compensation linked to the Company's perceived successes.

382. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.

383. Plaintiff, on behalf of Sage, has no adequate remedy at law.

PRAYER FOR RELIEF

FOR THESE REASONS, Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows:

a) Declaring that the Plaintiff may maintain this action on behalf of Sage and that Plaintiff is an adequate representative of the Company;

b) Declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Sage;

c) Determining and awarding to Sage the damages sustained, or disgorgement or restitution, by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest thereon;

d) Directing the Individual Defendants to take all necessary actions to reform and improve Sage's corporate governance and internal procedures to comply with applicable laws and to protect Sage and its shareholders from a repeat of the damaging events described herein;

e) Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

f) Granting such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: March 26, 2025

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